

Multinational Drug Corporations, Intellectual Property Rights and the Canadian
State: A Historical and Critical Analysis.

by

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A Thesis

submitted to the Department of Politics

in partial fulfillment of the requirements

for the degree of

Master of Arts

April 1996

Brock University

St. Catharines, Ontario.©

Abstract

This study critically analyzes the historical role and influence of multinational drug corporations and multinational corporations in general; the U.S. government and the Canadian state in negotiating the global recognition of Intellectual Property Rights (IPR) under GATT/NAFTA.

This process began in 1969 when the Liberal government, in response to high prices for brand-name drugs amended the Patent Act to introduce compulsory licensing by reducing monopoly protection from 20 to seven years. Although the financial position of the multinational drug industry was not affected, it campaigned vigorously to change the 1969 legislation. In 1987, the Patent Act was amended to extend protection to 10 years as a condition for free trade talks with the U.S. Nonetheless, the drug industry was not satisfied and accused Canada of providing a bad example to other nations. Therefore, it continued to campaign for global recognition of IPR laws under GATT. Following the conclusion of the GATT/ Trade-Related aspects of Intellectual Property Rights agreement (TRIPS) in 1991, the multinational drug industry and the American government, to the surprise of many, were still not satisfied and sought to implement harsher conditions under NAFTA. The Progressive Conservative government readily agreed without any objections or consideration for the social consequences. As a result, Bill C-91 was introduced. It abandoned compulsory licenses and was made retroactive from December 21, 1991.

It is the contention of this thesis that the economic survival of multinational corporations on a global scale depends on the role and functions of the modern state. Similarly, the existence of the state depends on the ideological-political and socio-economic assistance it gives to multinational corporations on a national and international scale. This dialectical relation of the state and multinational corporations is explored in our theoretical and historical analysis of their role in public policy.

Acknowledgements

The culmination of this thesis is a tribute to the direct and indirect collective contribution of quite a number of people. Unfortunately it would be difficult to single out each and every one for their due merit. However, sincere thanks and appreciation must be given to my supervisor Garth Stevenson who from day one stood behind me and helped to develop my ideas in undergoing this project. Thanks for your patience and cooperation. Also, to members of the thesis committee William Matheson and David Siegel for their help in reviewing this thesis and, to the external examiner William Coleman from McMaster University for his thoughtful and encouraging comments.

Initial interest into this topic began during my first undergraduate public policy class at Ryerson Polytechnic University in 1993. I therefore owe a special tribute to Arthur Ross of Ryerson who not only brought this issue to my attention but encouraged me to pursue further research investigations at the graduate level. To other members of the Department of Politics at Ryerson especially John Shields, Mike Burke, Myer Siemiatycki, and Caroline Wheeler for their encouragement and constant support. To Diana McLaren, Mariam Abdel-Salam and Verinda Mangat of the Continuing Education Students' Association of Ryerson for their tolerance, friendship and support. Thanks for bearing with me for so long.

Thanks must also be expressed to the University of Toronto Library staff for allowing me to use their facilities. Very special appreciation to Debra Drinkwalter of the Canadian Drug Manufacturers Association who introduced me to the literature of the industry and without whose help this project would not be possible. Thanks also to my friends Franz J.T. Lee, Clarence Lord and Albert Agyeman-Duah for their support. Finally to members of my family especially my mum, my brother who supported me throughout the period of my studies and to my sisters for their help. Also to all my nieces and nephews especially Ridwan, Faatimma and Stephanie.

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Introduction

Analytical Relevance of theme.

Access and availability of safe, effective and affordable medicinal drugs is a fundamental right and necessity for the protection of health and longevity of all humans especially, the sick and needy. They can prevent sickness, suffering, pain and disability. In this context, the success, triumph and hopes of human beings depend on the availability of collective intellectual resources and knowledge at their disposal for everyone's medical benefit. Therefore, the monopolization of knowledge through the state's protection of extended Intellectual Property Rights (IPR) under GATT/NAFTA for the multinational drug industry is an affront against those in need. In the first place, those who make decisions for the use of drugs are not the users; they only act as intermediaries, for example, the doctors or drug companies, who prescribe or produce medicines. For this reason, the above issue acquires great moral importance, because the sick are at their mercy and have no say in decisions that affect their health care.

Thus, it is relevant to investigate and analyze the various relations between the people's medical needs and the interests, whether they are political or economic, of the state, and of multinational drug corporations.

Current Research Work Done on the Theme.

As far as I am aware, not much has been written on this topic. However, there are some general works produced that are related to the topic but, they are not necessarily up-to-date. Most of them appear in the form of articles in magazines, newspapers and journals. Just to indicate a few contributors, we may mention authors, such as Joel Lexchin, Roy Davidson, and organizations, such as The Ecumenical Coalition for Economic Justice and the Canadian Drug Manufacturers Association.¹ Consequently, we have chosen to undertake this study, firstly because of its relevance to human health, and secondly, we have placed it within the historical context of the formulation of Canadian Public Policy.

Central Hypothesis.

Within the context of a globalized modern capitalist system there is a dialectical relation between multinational corporations in general, and the multinational drug corporations in particular, and the role and functions of the modern state. On the one hand, the state depends heavily for its existence upon its role to maximize the profits of multinational corporations on a global scale, and on the other hand, the multinational corporations cannot flourish without the functions, namely the ideologico-political and socio-economic assistance, of the state, as expressed in its national and international policies and projects.

¹. The work of the authors and organizations mentioned above can be seen in the bibliographic notes between pages 209 and 235.

In this thesis, I will attempt to verify the above hypothesis by accomplishing **five** objectives which correspond to the titles of individual chapters.

Objectives.

In this case, our five main objectives are as follows:

1. To describe and analyze important aspects of the multinational drug industry and its social and political impact on human health and the state.
2. To elucidate a theoretical analysis of the functions of the State, especially its ideological role in the formulation of Canadian Public Policy and Canadian/American relations.
3. To illustrate the historic development of intellectual monopoly pharmaceutical patent rights, the role of multinational drug corporations and state policy in Canada.
4. To analyze critically the historical process of Intellectual Property Rights on a global scale, with specific reference to the U.S. and Canada, within the framework of the emergence of GATT and NAFTA.
5. To analyze the role of the state, multinational corporations and Public Policy.

Methodology.

To achieve these objectives we find it necessary to apply a combination of certain methods:

- A. The historical,
- B. The analytical (deduction and induction),
- C. The descriptive and
- D. The Dialectical

The results of these and future perspectives will be formulated in the conclusion.

Chapter 1

Critical analysis of historic development of multinational drug corporations

General Introduction

The health and lives of millions of Canadians depend on the multinational pharmaceutical industry. The industry as it is today, is about sixty years old and has become the most profitable of all industries over the past thirty years. It is ranked first or second place in profitability of all U.S. industries.¹ Yet, it has consistently complained of a litany of factors, ranging from excessive government controls to the estimated loss of an average \$7-\$8 billion dollars annually² due to patent infringements and the high cost of research and development which it claims is reducing its profits. Pharmaceutical multinationals, it would seem, want to have it both ways: that is to have total control of the world market and to charge whatever prices they want, and meanwhile, to benefit from government's protectionist policies against competition through greater worldwide protection of intellectual property rights.

Since the advent of the Mulroney government to power in 1984, the Canadian health care system has experienced severe cutbacks in spending. It was estimated

¹. Andrew Chetley Healthy Business? World Health and the Pharmaceutical Industry (London and New Jersey: Zed Books, 1990) p-41. Also see analysis given by Roxanne Snider, "Patents and Profits." New Internationalists. August 1993.

². OECD Globalization of Industrial Activities, 4 Case Studies: Auto Parts, Chemicals, Construction and Semi-conductor (Paris, OECD, 1992) see introduction.

that since 1983, cuts in federal transfer payments under the Established Programs Financing (EPF) and the Canada Assistance Plan has resulted in a short fall of \$41 billion to the provinces.³ Federal transfers for the fiscal year 1992-93 were reduced by \$9.4 billion. These cut-backs have forced the provinces to reduce their health care budgets tremendously. Originally, the funding of health care was shared equally between the federal and provincial governments. In the 1970's, 50 percent of health care costs were paid for by the federal government but by 1993 the federal government had reduced its contribution to 24 percent.⁴ The new Chretien government promised to reduce health care spending from 10 percent of the GNP to about 8.5 percent in the near future. Ottawa's share of the costs of Medicare has consistently been reduced over the past years.

Doubts are currently expressed about the future success of the mandatory basic principles of Medicare: public administration, comprehensiveness, universality, portability and accessibility as stipulated by the 1984 Canada Health Act. As a result the brunt of the burden on spending on health care is now almost entirely left to the provinces. Most of them have responded by closing hospitals, reducing staff, merging certain services, cut down on hospital beds and longer waiting lists. Some provinces, for example Alberta and Quebec, have already

³. Canadian Center of Policy Alternatives. "The Tory Wreckord." (Ottawa: CCPA.1993)

⁴. *ibid.*, p-29

suggested that cut backs in regional transfer programs are forcing them to look at alternatives to the present system. Alberta is presently pursuing plans to introduce a two-tier system through user fees while Ontario and Quebec are already planning to privatize certain services. Other services including drug benefit plans for the poor and elderly are being reduced in some provinces. Alberta is presently contemplating privatizing this essential service, while provinces in the Atlantic region have said they can no longer afford such a service.

The former Tory government's philosophy to favour the conglomerate financial interests of multinational drug companies above the need of Canadian citizens and the health care system is evident in high costs of pharmaceutical drugs today. According to the Canada National Health Expenditures report of 1975-93 "expenditures on drugs continued a decade long trend of being the fastest growing component of estimated health spending. In 1993, drug spending increased by 8.2 %. The annual rate of increase in drug spending was 8.6 % in 1992 and 10.9 % in 1991."⁵ In 1993 Canadians spent an estimated \$72 billion on health care or about \$2,507 per person of which the costs of drugs represented 15.1%.⁶ The 'shot gun' approach to Canada's pharmaceutical policy by the Tory government, to pass the Drug Patent Act Bill C-91 on the pretext that it was mandated to do so by GATT

⁵. National Health Expenditures in Canada, 1975-1993. Health Policy and Information Directorate. (Ottawa: Policy and Consultation Branch, Health Canada, 1994)

⁶. *ibid.*,

and NAFTA, is a severe blow to the Canadian health care system. Consequently, Canadians are again paying one of the highest costs for prescription drugs in the world. Bill C-91 extends monopoly patent protection rights to multinational drug companies from a period of 10 to 20 years. This move by the Tory-led government will abolish price competition for an additional 10 years.

Cut-backs to the funding of health care by both the federal and provincial governments to stem increasing costs are combining to create a crisis in the provision of health services to the public. To make matters worse, according to the Center for Policy Alternatives, the U.S. - Canada Free Trade Agreement permits U.S. firms to take over the management of Canadian hospitals, nursing clinics and homes, medical and research laboratories, alcohol and drug treatment centers and ambulance services. Also, under the provisions of NAFTA all services offered by government including the health care system are open to privatization.⁷ According to U.S. consumer advocate Ralph Nader, "nothing irritates the hospital industry, the drug industry, the doctors' lobby, the insurance lobby in the U.S. more than the Canadian universal health system,"⁸ and as a result it is targeted to be destroyed since Americans "cannot bear the presence of an alternative model north of the border where people in the U.S. can look to."⁹

⁷. Center for Policy Alternatives, op. cit. p-29

⁸. Toronto Star. "U.S. Lobby backs drug bill , Nader insists." December 1, 1992, p-A2

⁹. *ibid.*,

The exclusive 20-year monopoly protection from competition for foreign multinational drug companies does not by any means help the already fragile health care system. According to Ontario's Health Minister Frances Lankin Bill C-91 would cost her province another \$1-billion over the coming decade.¹⁰ The New York Times has estimated that Canadians will as a consequence pay an additional \$508 million annually for drugs or a 12 percent annual increase in prices. According to the New York Times report "The added cost would grow to about \$800-million [about \$1-billion Canadian] by the late 1990's."¹¹ Other financial analysts have estimated that costs will rise to about \$1 billion annually because of Bill C-91, since the costs of Canadian produced generic drugs are about 30-40% lower compared to the foreign multinational based products.¹² This savings emphasizes the need again for a solid and dynamic local industry to compete with the foreign owned.

Traditionally one of the most significant aspects of Canada's social welfare tradition and its health care policy is that those with low incomes who are ill should not suffer the consequences of not having access to prescription drugs. It has been estimated that the poor in Canada spend a higher proportion of their income on prescription drugs than the wealthy.¹³ The poor at the same time are forced to spend

¹⁰. Globe and Mail "Report says drug patent law will cost Canadians billions." November 17, 1992, p-A11

¹¹. *ibid.*,

¹². Ruth Scher. "Patent Greed." The Facts Vol. 13, No. 3, December 1992. p-39

¹³. Joel Lexchin. The Real Pushers. (Vancouver: New Star Books, 1984) p-34.

less money on prescription drugs compared to the wealthy because of financial reasons. It is argued therefore, that illness is inversely related to the level of income.¹⁴ The increased costs of drugs will severely affect, also, senior citizens who make up only 11 percent of the population but consume 40 percent of drugs sold in Canada.¹⁵ According to a report by Patterns of Health Care in Ontario, the costs of prescription drugs sold to senior citizens more than tripled between 1985 to 1993. During this period payments under the Ontario Drug Benefit plan for senior citizens increased from \$212 million to \$645 million.¹⁶ Edith Johnson of the National Senior Citizens Federation, in an interview with the author, noted that the passing of Bill C-91 "would worsen the problem of access to quality health care to senior citizens since they will suffer from reduced provincial governments' contribution to Drug Benefit Plans because of higher costs of prescription drugs."¹⁷

The Canadian Patent Act already guarantees 20 years patent protection for medicines invented and developed here in Canada. However, the multinational drug industry has chosen to carry out most of its research and development on new medicines outside of Canada. This emphasizes a need for a strong and vibrant

¹⁴. *ibid.*, p-39

¹⁵. House of Commons Debates. November 17, 1992. p-13507.

¹⁶. Toronto Star "Seniors and Drugs." June 8, 1994. p-A21

¹⁷. Edith Johnson. President of National Senior Citizens Federation. Interviewed by Author, June 25, 1995.

domestic industry that will not only create jobs but reinvest earnings in the local sector.

In this chapter, although referring to the international multinational drug industry, we will be mainly concerned in giving a historical review and analysis of its history and structure, the role of research and development, safety and high costs of drugs, profits, the power and influence of the industry and finally its marketing and advertising campaign. An appreciation of the inside workings of the drug industry will help us to understand yet another aspect of its role of power and influence in conjunction with the United States government to institute new international intellectual property rights regulations within GATT and NAFTA. This task, needless to mention, was made much easier by the complacent and encouraging actions by the Canadian state under the guidance and tutelage of the Tory government. Also excellent support was given by the Canadian business lobby which by and large is dominated by many U.S. subsidiaries. In the next chapter, we will analyze the theoretical perspectives of the State and public policy.

History of Multinational Drug Industry.

Most of today's pharmaceutical companies are offsprings of the European and particularly the German chemical industry that provided the basis for some of the early and most important drug discoveries. Significant contributions to the discovery of new drugs were made in the mid- and late- nineteenth century. Some important discoveries during this period, such as anesthetics, were nitrous oxide

(1844), ether (1846), and Chloroform (1847). For anginal pain, amylnitrite (1867) and nitroglycerine (1879) were used. During this period the introduction of synthetic drugs served as a tremendous break-through for the relief of pain and fever, especially the discovery of yrene (1833), acetanilid (1886), and acetophenetidin (1887). These important discoveries contributed to the transformation of the chemical industry into the pharmaceutical field thus affecting production of pharmaceuticals until 1914.¹⁸

Because of World War I, the British, French, and Americans were cut off from vital supplies of pharmaceutical drugs and synthetic chemicals from Germany that severely affected their medical care programs. They were soon forced to establish their own chemical industries to alleviate the suffering of their population. The approach adopted by these nations including the U.S. was the duplication and copying of brand name products already created by German scientists and drug companies.

In 1935, the German parent company of Bayer and Hoechst, IG Farben Industrie discovered Prontosil, a derivative from red dye. It was subsequently thought to be a very effective treatment against infections including pneumonia, scarlet and childbed fever and urinary infections. Two years later French scientists discovered that the active ingredient of the Prontosil was not red dye itself but

¹⁸. Milton Silverman and Philip R. Lee Pills, Profits and Politics. (California: University of California Press, Ltd, 1994.) p-4

sulfanilamide which was already discovered in 1908 but was not recognized for its germ-killing properties.¹⁹ The recognition of sulfanilamide (the first sulfa drug) paved the way for the creation of other 'wonder drugs', such as penicillin, streptomycin, tetracycline (the first broad-spectrum antibiotics), cortisone and hydrocortisone. Other significant discoveries followed with the introduction of important antibiotic derivatives such as ampicillin and erythromycin. Similar and other related innovations continued and new areas of therapy that were not previously susceptible to drugs were opened.²⁰

However, the success of new medical discoveries as evident above will lead to an ever lasting impression of an over zealous and opportunistic industry which was not only dedicated to curing of diseases but also the wanton killing and drugging of millions of persons as documented below. In a series of damaging reports during the late 1920's and early 1930's the industry was found guilty as a pusher of illegal drugs, namely heroine and cocaine based products designed specially for public consumption.

Elmer Bobst, a former president of Hoffmann-La Roche, confirmed in his autobiography that his company was "heavily involved in the supply of morphine to the underworld between the two world wars." A trial in 1925, in Shanghai,

¹⁹. Chetley. op.cit. p-19

²⁰. For more information on this topic see, Silverman and Lee, op. cit. p-4, Chetley, op. cit. p-19

confirmed that Hoffman La Roche shipped 180 "chests of opium" from Istanbul to China, also "26 boxes containing mostly heroin, imported from Basle, Switzerland by a Chinese dealer, Gwando." According to Sir John Campbell, chairman of the British delegation to the League of Nations Opium Advisory Committee, meeting in 1927, where another case of trafficking was discussed, he "had no doubt whatever that Hoffman La Roche and Company was not a firm to which a license to deal with drugs should be given." This was not by any means an isolated incident. At the turn of the century another drug company known for the discovery of aspirin, Bayer, promoted the using of heroin "as a panacea for infant respiratory ailments." Yet, another well known pharmaceutical giant Parke-Davis was also found guilty of a similar act. It developed "coca-cordial, cocaine cigarettes, hypodermic capsules, ointments and sprays," for consumer sale.²¹

During the Nazi occupation of Poland, some drug companies made agreements with the Nazis to test their products on Jewish and other inmates at Auschwitz. IG Farben Industrie of Germany established a chemical plant close to Auschwitz with the sole purpose of carrying out experiments using inmates from the concentration camp for testing of new drug products. In one of the tests, all 150 inmates died.²² According to The News World, IG Farben also produced "Zyklon-

²¹. John Braithwaite. Corporate Crime in the Pharmaceutical Industry. (London: Routledge and Kegan Paul. 1984) p-206. Also see Chetley op.cit. p. 16-20

²².Chetley. op. cit. p-19.

B to gas inmates of the Nazi concentration camps." It also forced more than 350,000 inmates to work in slave camps with "30,000 of them in Auschwitz."²³ After the second world war IG Farben was liquidated and broken up into BASF, Hoechst and Bayer. During the Nuremberg war crimes trial, 12 senior drug executives were sentenced to prison. However, by 1955 one of the jailed executives became the chairperson of Hoechst and in 1956 another became chairperson of Bayer.²⁴ Evidence of these crimes "are conveniently forgotten by today's executives as they plot the course of the industry in its modern incarnation as a health care products industry."²⁵

Maybe one can argue that the past is the past and it has little bearing on the future. However, would it be possible to separate the present and future from the past? Again, the drug industry has consistently provided the answer. But it is interesting to note that "people who foster dependence on illicit drugs such as heroin are regarded as among the most unscrupulous pariahs of modern civilization. In contrast, pushers of licit drugs tend to be viewed as altruistically -motivated purveyors of a social good."²⁶

The drug industry has developed from a pusher of cocaine and heroin-based

²³. The News World "IG Farben may compensate WWII labourers." August 10, 1995. p-10

²⁴. Chetley. op. cit. p-19

²⁵. *ibid.*,

²⁶. Marshall Clinard. Corporate Corruption, The Abuse of Power. (New York: Praeger Publishers, 1991) p-58.

products to the "purveyors of social good" through an extensive use and promotion of psychotropic drugs such as, antidepressants and tranquilizers in the 1950's. This period was known for its greatest innovative boom of the pharmaceutical industry. Important break-throughs were made on steroids, oral contraceptives, anti-diabetic and cardiovascular drugs. Also with the help of the introduction of the first sulfa drug the pharmaceutical industry was radically transformed. According to Silverman and Lee, this period "heralded the start of the great drug therapy era."²⁷

Patents and Pricing of Drugs.

Equally important during this period was the recognition of the important role of patents and the pricing of drugs for the industry. Not all the derivatives from sulfa, for example, penicillin, cortisone and hydrocortisone, were patented. Later, improved versions of these drugs were developed such as streptomycin which was introduced commercially in 1946. However, the patents were licensed widely and most drug companies produced generic versions sold at significantly reduced prices. Penicillin for example was sold in 1945 for \$60 (10 million units bulk), \$4.75 in 1950 and \$0.21 in 1960. The cost for streptomycin dropped from \$160 (10 grams bulk) in 1946 to \$3.15 in 1950 and to \$0.36 in 1960.²⁸ From this dramatic drop in the prices of drugs, the lesson was clear to Drug manufacturers that price

²⁷. Silverman and Lee. op. cit. p-4.

²⁸. Gary Gereffi. The Pharmaceutical Industry and Dependency in the Third World. (Princeton: Princeton University Press, 1983.) p-107.

competition was detrimental to their financial interest.

To avoid future price competition, drug manufacturers used their patent rights to protect and control the production of new drugs. According to Garry Gereffi, as a consequence "firms were able to restrict output of their own drugs to levels where monopoly profits could be maximized."²⁹ It also simultaneously increased the importance of advertising as an alternative to price competition within the drug industry.

Structure of Pharmaceutical Industry.

The pharmaceutical industry is dominated by a relatively small group of oligopolistic multinationals and many small companies that produce mainly generic and over-the-counter medicines. Sixty percent of the domestic market in Europe is controlled by a few multinationals.³⁰ Drugs produced by these multinationals such as ICI and Glaxo of England, Hoechst and Bayer of Germany, Ciba-Geigy, Sandoz and Hoffmann-La Roche of Switzerland account for a large portion of sales in their home market. The U.S. home market is largely dominated by a few large U.S. firms such as Merck Frost, the world's largest and most profitable producer, American Home Products, Pfizer, Eli Lilly, Abbot Laboratories, Bristol-Myers Squibb corporation, Johnson & Johnson, Smithkline Beecham and Rhone-Poulenc Rore

²⁹. *ibid.*, For a detailed analysis of the above information read the information provided by Geriffi in his footnote on the same page.

³⁰. OECD. Globalization of Industrial Activities, 4 Case Studies: Auto Parts, Chemicals, Construction and Semi-conductor. (Paris: OECD, 1992) p-67

Inc.³¹ The Japanese pharmaceutical firms are much smaller compared to those of Europe and the US. In Japan the top five firms account for an average of \$1 billion in sales annually compared to \$3 billion per year for the top five European and American firms.³²

The world's growth and production of pharmaceutical drugs have almost doubled since 1975 to \$150 billion in 1990 while the world consumption on a per capita basis rose from \$17 in 1975 to \$29 in 1990. Three-quarters of the world's consumption is reported from the industrialized world, while the remaining comes from the developing and less developed countries. Around two-thirds of the world's production of pharmaceuticals is produced by about 25 multinational corporations, while the rest are produced by smaller companies.³³

The rapid growth of world consumption of pharmaceuticals has contributed to the internationalization of the industry that is heavily concentrated with many mega-mergers and acquisitions among large drug companies. Most recently a new phenomenon in pharmaceutical investment was undertaken in the US. Many large multinational drug companies are merging with the health insurance industry to take control of hospitals, clinics, nursing homes, pharmacies and doctor's practices.

³¹. *ibid.*, p-66

³². *ibid.*, p-67.

³³. Robert Ballance Janos Pogany and Helmut Forstner The World's Pharmaceutical Industries, An International Perspective on Innovation, Competition and Policy. (London: Edward Elgar Publishing Limited,1992) p-4 and 5.

Merck, the largest drug manufacturer, took over a company that "manages the health benefits of 33 million Americans for nearly 60 times that company's earnings."³⁴

Another drug giant Eli Lilly paid some \$4 billion for PCS, the largest managed health care company in the U.S., which administers health care plans for 50 million Americans.³⁵

In April, 1995, the author asked Cam Bailey of Eli Canada if similar takeovers are planned here in Canada. His response was "I don't think so."³⁶ A few weeks later it was announced that Eli Lilly had bought Rx Plus, Canada's second largest manager of pharmacy benefits. Fears are now being expressed that similar takeover of pharmacy benefits programs such as Green Shield and Shared Health Network Services by drug companies are in the making that could jeopardize the sales of cheaper generic drugs. Jim Keon, the vice-president of the Canadian Drug Manufacturers Association sees the move by Eli Lilly as "a dangerous precedent."³⁷ The take over of other pharmaceutical benefit programs could place yet another important component of Canada's health care system in control of the multinational drug industry and prevent the supply of cheaper drugs. The control and domination of Canadian markets by multinational corporations are the highest of all

³⁴. Maude Barlow. The Assault on Health Care-A Time to Act. (Ottawa: Council of Canadians. mimeo, 1993) p-4.

³⁵. *ibid.*, p-4.

³⁶. Cam Bailey of Eli Lilly. Interviewed by Author, Scarborough, Ontario. May 1995.

³⁷. Toronto Star "Lilly buys drug-plan manager." (May 12, 1995) p-E7

industrialized nations. Some 92 percent of the Canadian drug market is controlled by foreign multinationals.³⁸ The European pharmaceutical markets are quite distinct. The local production of pharmaceuticals by foreign firms accounts for 60 per cent in Spain, 50 per cent in France, Italy, and Austria, 35 per cent in Britain, 20 per cent in Germany, the Netherlands and Scandinavian countries. Most foreign investments in Europe are by Swiss multinationals which account for 50 per cent of sales and American multinationals which account for 20 per cent. Foreign investments in the US account for just 18 per cent of the U.S. market. In Japan 15 per cent of local production is accounted for by foreign multinationals.³⁹

Research and Development.

The question of research and development is the most contentious issue that has beset the functioning of multinational drug companies. The drug industry claims that it spends as much as \$250 million to develop a drug. Much suspicion and mistrust surround the true application, meaning and purpose of the term 'research' as used by the industry. Quite naturally it is an important factor for the survival of multinational pharmaceutical industries. For some it invokes a depiction of meticulous looking scientists dressed in spotless white coats, gloves and goggles surrounded by several test tubes, computers and other equipment. Whatever picture it conjures in the mind is one of conscientious scientists working for the benefit of humanity. Nevertheless,

³⁸. Eastman, op.cit. p-28

³⁹. OECD report. op. cit. p. 72-73.

this image can be deceiving.

For the industry, as part and as parcel of its campaign to win sympathy and support from consumers and government decision makers, the regular procession of charts and diagrams in magazines shows savings to the health care system due to the introduction of advanced medical discoveries that save lives and prevent diseases. There is no doubt that advanced medical discoveries attributed to research and development save lives and prevent some diseases. But another contributory factor to the general improvement of health of humans is the increase of living standards, better nutritional and hygienic standards.

The term research is subject to wide interpretation that often helps multinational drug companies to hide many non-research related activities as research and development. Drug companies have consistently refused to open their books to the public to prove what it really costs to produce a drug. Therefore, there are doubts as to how much it really costs to undertake a research project. Within the multinational drug industry the cost of research and development does not restrict itself to pure scientific development of a drug but also includes the costs of promotional expenses for doctors, conferences, surveys and supplies of large amount of samples to patients for testing and promotions on humans. These 'extra research' related activities are calculated as monies spent by the industry for research and development and are all subjected to tax breaks from government. In the departments of sales, research also includes the expenses incurred in the testing

of products, to find out the preferences between consumers and health care practitioners.

Finally, and most importantly for the scientific division of the firm, research means "the trial of certain chemicals or biological products in perhaps hundreds, if not thousands, of combinations and formulations to develop a specific drug."⁴⁰ Added to the industry's effort is research carried out at public expense in hospitals, universities and government-run laboratories. Drug companies can reduce their risks in R & D by obtaining substantial tax breaks and other encouragement from governments. They buy research from other scientists, and are recipients of benefits from basic research conducted in government and university labs. The knowledge of the latest scientific discoveries is shared and acquired world wide from scientific magazines and other publications to better the service of health care.

The massive innovative boom by the pharmaceutical industry that started after World War II, reached its apex in the 1950's and continued at a steady pace in the 1960's, with a series of new discoveries, but has slowed considerably in the 1980's and 1990's. It has been argued that the annual total of new chemical entities introduced into the world market decreased dramatically "from 93 in 1961 to 48 in 1980."⁴¹ This effectively put the drug industry in a deep crisis, and has contributed

⁴⁰. For the historical data provided on this topic see., Alan A. Klass. There's Gold in Them Thar Pills. (Great Britain: Penguin Books, 1975.) p.20-24. Also see Chetley, op.cit p. 31-50

⁴¹. Robert Chew. et al, Pharmaceuticals in Seven Nations. (London: Office of Health Economics, 1985.) p-27.

to a world wide industry campaign to push national governments for greater protection in intellectual property rights. A major reason that explains why the industry is in an innovative crisis is its policy of carefully selecting which research projects to undertake, that is based only on the possible financial gains to be made and not on how many lives can be saved or on how many diseases can be cured.⁴²

The role, influence and analysis of the stockbrokers in advising their clients and shareholders of the industry whether to invest or discard their shares is the most important determinant in influencing the industry's research strategy.⁴³ This information is based on the market and demand for a particular drug and the amount of profits to be gained from its sale.

The industry is also able to diminish the cost of its research and development in many ways. To avoid expiring patents, they manufacture "me-too" drugs by reproducing medicines through slight modification of the molecular formula of the active ingredient of medicines discovered to be successful. The problem of this type of reproduction is that it beguiles the public into thinking that the industry is innovative. For example, an evaluation of 508 new chemical entities (NCEs) introduced from 1975 to 1984 shows that only 7 percent involved a new chemical

⁴². Drake and Uhlman. op.cit. p. 65-85

⁴³.Mike Muller The Health Of Nations (London: Redwood Burns Ltd. 1982) p-63, Also see Chetley, op.cit. p.41-50

formation of important therapeutic advancement.⁴⁴ According to Drake and Uhlamn 53 per cent of 258 drugs approved in the US for the decade ending in 1991 were "me too" drugs. But, while there is an abundance of drug products developed, an F.D.A report revealed that between 1967 and 1984 of the 3443 drugs products on the market only 12 percent could be rated as "effective for all the indications claimed, while 40 percent of the products had no effective indication."⁴⁵ This report raises serious questions with regards to the merits of investment on research and development. Here in Canada, according to a study conducted by the Patented Medicine Prices Review Board, between January of 1988 to December 1990, of the 162 new drugs introduced only 8 represented a significant breakthrough for the sick.⁴⁶ Another report, this time by the U.S. special committee on aging, noted that 84 percent of new drugs introduced to the market between 1981 and 1988 were of "little" or "no therapeutic gain." Drug companies, according to the report, "passed on to consumers about \$37 billion for research and development to produce 292 new drugs with little or no potential therapeutic gain over existing drug therapies." The U.S. study was quoted in a report by the Department of Consumer and

⁴⁴. Michael Tan Dying for Drugs? Pill, Power and Politics in the Philippines. (Hain: Health Action Information Network, 1988.) p-80.

⁴⁵. *ibid.*, p-81.

⁴⁶. Globe and Mail "Higher costs for health care, higher profit for industry." January 18, 1993. p-A-15.

Corporate Affairs which was ironically influential in the introduction of Bill C-91.⁴⁷

Another conspicuous characteristic of today's drug industry is its tendency to avoid taking risks in undertaking research projects that show not much sign of some substantial profits. Many analysts have concluded from time to time that drug companies abandon ongoing research on potentially effective drugs if statistical and other financial analysis reveals that the expected profit is not going to be big enough.⁴⁸ As a result, they allow others like government agencies, university labs and private individuals to do basic or introductory research until gains can easily be forecast. Once there are signs that the results would potentially pay off, then drug companies get involved in the project which leads to increased prices. One can therefore argue that the high cost of drugs does not necessarily reflect the costs of R & D and the level of protection of intellectual property rights as the following examples demonstrate.

Through a \$11 million grant from the National Cancer Institute to researchers of the Mayo Comprehensive Cancer Center in the US, the drug Levamisole, which was previously used on sheep to get rid of parasites, was successfully tested as a cure for colon cancer. Formerly, it was sold for about \$14 to farmers by Johnson & Johnson for a year's supply but, after its successful test for colon cancer, the price

⁴⁷. Toronto Star. "Ottawa just says yes to drug firms." January 18, 1993. p-A15.

⁴⁸. Donald Drake and Marian Uhlman. Making Medicine, Making Money. (Kansas City: Andrews and McMeel, 1993.) p-67.

rose to \$1,250 to \$1,500 for the same amount by the manufacturers for human use. Similarly, the drug AZT (brand name Retrovir) was discovered by US government-funded scientists in Detroit for the intended use on cancer patients in 1964. Since the drug was not effective in treating cancer it was ignored for more than two decades. After the discovery of AIDS, Burroughs Welcome tested AZT on AIDS patients and it proved to slow the course of the disease. AZT, which was originally discovered at American taxpayers expense in 1964, is now sold for thousands of dollars to AIDS patients.⁴⁹ The cost in Canada is estimated at about \$2,000-\$3,000 for a month's supply.

Safety of Drugs

The safety of drugs is a human, moral and ethical obligation on those who have the responsibility of manufacturing and marketing drugs for the public consumption. While it has already been suggested that the pharmaceutical industry is not motivated by altruism but by profit for survival, regard for the public ranks to the bottom. In any given year in the U.S.,

⁴⁹. *ibid.*, p-67.

30,000 people will die from adverse drug reactions, 80 percent of which are thought to be preventable. An additional fifty to a hundred thousand persons will die from drug-resistant killer forms of bacteria whose emergence has been stimulated by the misuse and over prescribing of antibiotics.⁵⁰

It has also been calculated that 18 to 30 percent of patients in all hospitals double their period of hospitalization due to severe adverse reactions to drugs, while about 1.5 million people are hospitalized annually from adverse reactions.⁵¹ Profits and services to the public do not necessarily go hand in hand. It is the essence of a contradiction that ridicules the interest of consumers through an ideology of deceit.

From the very inception of the drug industry the question of safety has been an issue of concern to millions of consumers. No precise figures are available at this moment as to the number of violations of Federal laws in Canada. Nonetheless, an American study by Fortune magazine (reported by Clinnard Marshall 1990) reveals that the pharmaceutical industry has "racked up a far worst record of Federal law violations than any other industry except oil and automotive."⁵² It is "involved in 1 out of every 10 cases of violations, and 1 in 8 cases of serious violations," which also includes the making of unsafe products in the U.S. "One out of 10 of all the penalties the government imposed on large corporations for serious violations were

⁵⁰. Marshall Clinard and Peter Yeager. Corporate Crime. (London: The Free Press, 1980.) p-262.

⁵¹. *ibid.*,

⁵². Clinard and Yeager. *op. cit.* p-62

levied on the pharmaceutical industry."⁵³ The study also reported that one corporation alone had violated federal laws 21 times within a two-year duration.

The pharmaceutical industry prides itself as an ethical industry charged with the responsibility of saving lives. However, the process of accountability, honesty and integrity is very much to be desired. Of great concern to many are the number of cases of fraud and falsification of data on clinical trials, false information provided by drug companies and the hiding and misrepresenting of dangerous effects of drugs that are sold on the market. (see examples below) It is not possible to relate all or rank in importance the number of cases of violations that have been reported since there are so many to choose from. Given the present conditions under which drugs are manufactured and promoted, it is very difficult to detect fraud and falsification of data provided by drug companies. Drug companies are often found guilty of withholding important information on effects of a drug that is vital to the life of the patient as the following example proves:

⁵³. *ibid.*, p-56

In early July 1978, an ambulance rushed June Froman to a hospital in New York City. Froman, a patient of Dr. Jerome Rotstein, had been tested for a severe case of arthritis with an experimental drug called Sudoxican, manufactured by Pfizer Company. Rotstien was supposed to be monitoring Froman's use of Sudoxian carefully in late June and early July, and was supposed to report any unusual reactions to federal officials. Instead of conducting monitoring tests, however, Rotstein went on vacation in Europe. By the time he returned, Froman had already been admitted to the hospital, her liver dissolved by sudoxican. "In no way could she be saved, no matter what we did for her," Rotstein told FDA officials later. But Rotstein pointed the finger of blame for death at Pfizer Company officials, claiming they hid the drug's serious adverse effects from him and tried to convince him not to report the death to Federal authorities. "It is a killer drug." Rotstein said. "I killed a patient because I didn't know the drug caused hepatic toxicity. I was led down a blind alley by people who should have known better." Alerted by the news of Froman's death, FDA investigators reviewed reports that Pfizer had submitted to the FDA. Strangely these reports included results, purportedly from Froman's case, recorded up to several days before her hospitalization, that showed "essentially normal clinical studies." After investigators examined the clinical studies closely they found that Rotstein had been out of the country and had never done any of the studies. If Froman had not died, the FDA might well have accepted the falsified Sudoxican tests, and millions of Americans could have been exposed to her fate.⁵⁴

The dilemma of suppression of facts by drug companies is a rampant practice which has reached alarming proportions; fortunately for consumers the drug Sudoxican was not launched on the market. However there are many other drugs whose effects are known to drug companies but have not been revealed to the relevant state regulatory bodies. A good example in point was a confession by Eli Lilly to the British Parliament and American Congress that it knew of the dangers of its anti-arthritic drug Opren, before it was launched in the U.S. It killed 74 patients

⁵⁴. Braithwaite, op. cit. p-54.

in Britain, 15 months before the drug was withdrawn from the market. (Sunday Times, 27 February 1983) One year before its withdrawal, an investigator for F.D.A recommended that criminal charges be brought against Eli Lilly for failing to report 65 of 173 adverse reactions on four brands of drugs submitted by doctors including Opren. Yet Eli Lilly continued to market the drug. (Wall Street Journal, 4 August 1983).⁵⁵

Drug companies are not only guilty of withholding vital information to the public, but doctors under the payroll of these companies to monitor safety tests are also culpable as well. According to the F.D.A, between 1977 and 1980, 62 doctors were found to have submitted falsified or incorrect clinical data to the organization.⁵⁶ It is alleged that drug companies purposefully hire doctors whom they think can easily manipulate tests results to get F.D.A approval. Between 1971 to 1978, Dr. Ronald Smith was hired by six drug companies including Sandoz, Upjohn and Cyanamid to carry out tests on about a dozen psychotropic drugs. Luckily, according to an F.D.A scientist, an office assistant reported that "the way the doctor got the pill count to come out correct was to count the correct number of pills the patient should have taken and then flush them down the toilet."⁵⁷

The job of the Food and Drug Administration in the U.S., is made more

⁵⁵ Braithwaite. op. cit. p-56

⁵⁶. ibid., p-53

⁵⁷. Braithwaite. op.cit. p-53

difficult in tracking down alleged irregularities by doctors working on behalf of drug companies to carry out research. Attempts by the F.D.A to investigate some physicians on the quality of data they have submitted for approval for new drugs have resulted in unexplained calamities. For example, Dr. James Scheiner who works on behalf of Johnson and Johnson had his office broken into on the eve of an F.D.A investigation. All his records related to his research to be audited were thrown in his whirlpool bath. Before his next scheduled FDA audit, his office was set on fire. Another doctor Francois Savery "**accidentally**" dropped his statistics collected for Hoffman-La Roche and other companies overboard while in a boat when he was informed of an impending F.D.A. investigation.⁵⁸

It is alleged that pharmaceutical companies put immense direct and indirect pressure on outside laboratories and specialists to give them commendatory test results. Drug companies are anxious to get their drugs on the market and therefore select laboratories interested in making profits and which will give them favourable results. Any unfavourable submission of results would mean the loss of future contracts.⁵⁹ Consequently, the falsification of data to prove positive results is a regular practice among commercial laboratories.⁶⁰ Another appalling drug testing fraud involved Mer/29, a drug designed to reduce blood cholesterol by Richardson-

⁵⁸. *ibid.*,

⁵⁹. Clinard and Yeager, *op. cit.* p-63

⁶⁰. *ibid.*,

Merrill. The company submitted to the F.D.A that tests were carried out successfully on over 300,000 patients before approval was granted. Months later patients were complaining of baldness, changes to blood and reproductive organs and serious damages to eyes and skin. According to Marshall Clinard "it turned out that when test monkeys, dogs, and rats became ill or died, test supervisors ordered testing personnel to change the test data and even to substitute healthy animals for the sick group,"⁶¹ as a ploy to deceive the F.D.A. The result from this deliberate deception was the sickness and suffering of thousands of patients who later died. Similarly, when G.D. Searle was charged for fraud and incompetence in 1970 for the false testing of Aldactone, Flagyl and Norplace, the company admitted to a grand jury trial that "while there might have been a little dishonesty here and there, basically it was a problem of incompetence and poor recording among our research staff."⁶²

In the 1960's perhaps one of history's most despicable drug disasters occurred despite warnings that the drug Thalidomide, prescribed to help prevent nausea in pregnant women, could cause malformations in the foetuses. As a result more than 10,000 babies were born limbless and crippled. Nonetheless, the manufacturers, Merrell company, maintained that the drug was safe despite overwhelming evidence to the contrary until the worldwide birth defects reached alarming proportions in

⁶¹. *ibid.*,

⁶². *ibid.*,

Europe and North America. The drug was eventually withdrawn from the European markets in 1961 but was not taken off the shelves of Canadian pharmacies until one year later.⁶³

The incompetence and corruption practiced by drug companies have similar ramifications for Canadian consumers, since not all drugs approved by the F.D. A are retested here in Canada. In 1992 in a bid to 'harmonize' Canadian testing policy with the U.S., the Conservative government announced new measures to speed up the approval of new drugs by reducing the participation of its own experts. Responsibilities for the reviews of over 100 new drugs were handed over to private consultants; most of whom have worked with some drug companies involved. This favourable shift in policy from the stand point of drug companies came after years of lobbying by the industry who complained of long waiting periods to get their drugs approved. According to Health Minister Benoit Bouchard, the aim of the policy was to reduce the approval process from four to six years to about six to twelve months. The government's decision came in the wake of a study conducted by the U.S. General Accounting Office on ten years of drug review of the F.D.A, which revealed that "drugs with serious post-approval risks had a shorter approval time than drugs without such risks." Between 1976 and 1985, the study found that 102 of 198 drugs approved by the F.D.A had "serious post-approval risks." Some of these

⁶³. Lexchin., op.cit. p-193

drugs were later approved by Canadian authorities here in. As a consequence the F.D.A called for stronger reviews and brought to attention the case of Dow Corning, manufacturers of silicone breast implants. Internal documents released by Dow Corning revealed that the company knew since the mid-1970's that its implants would leak.

Previously, reviews of proposed new products were conducted by the Health and Welfare Department's protection branch based on information submitted by drug companies and the F.D.A. Now these reviews are given to private researchers "some of whom also receive fees from drug manufacturers for conducting research." The safety of Canadian drugs is now compromised and according to Joseph Valadares, a HPB pharmacologist with 22 years experience, "We're getting a higher percentage of positive reviews from outside reviewers" For Sari Tudiver of the Winnipeg Women's Health Clinic "Drug approval in Canada is [now] a closed process. It includes the drug industry but no consumer input."⁶⁴

Profits, Prices and Power of Influence

There is much ambiguity and tension between the role of the industry as guardians of the public's health and its emphasis on the maximization of profits. The public pays billions of dollars for pharmaceutical drugs through inflated prices often beyond the reach for those who really need them. Yet it has been calculated that in

⁶⁴. Note all the above quotations and information on this topic are taken from the Globe and Mail. "Is drug policy pushing the limits. Ottawa draws fire for seeking to speed producers' approval." February 25, 1992. p-A1,A6

any given year the same public are the big losers since they cannot be guaranteed they will be cured.

Pharmaceutical drug companies are ranked among the most profitable industries in the world. In 1991, while other American industries were experiencing declining profits in the United States, pharmaceutical companies earned 15 to 20 percent more than the previous year. For every dollar invested by the industry it was making 26 cents profit which is twice the rate of return compared to all other of Fortune's 500 industries. Their financial performance exceeded the performance of the auto sector by twenty-six times, oil and publishing by three and two times respectively.⁶⁵ While individual drug companies have also been making record profits, Merck & Co, the world's largest pharmaceutical company, earned forty-six cents profits out of every dollar invested.⁶⁶ According to Drake and Uhlman, there is no other business in the U.S. that consistently makes such enormous profits despite the economic situation.⁶⁷ In 1990, American consumers spent some \$67 billion on prescription drugs. It was estimated that their prices increased at three times the rate of inflation in the 1980's -a 152 percent increase.⁶⁸ According to Roxanne Snider, American-based drug companies earned profits of 15.5 percent on sales compared

⁶⁵. Drake and Uhlman, op. cit. p-5

⁶⁶. *ibid.*, p-6

⁶⁷. *ibid.*,

⁶⁸. Viveca Novac "The Other Drug Lords." International Journal of Health Services. Vol.23 Number 2, 1993. (New York: Baywood Publishing Co, Inc) p-264

to an average of 4.6 percent for other major based industries, while the 20 highest paid executives in the United States work in the drug industry with an average salary between \$5.8 and \$8.4 million a year.⁶⁹

Excessive profits breed power and authority within the American decision making process because much more money can be spent freely among key congressional figures. It is argued that "nothing happens on Capital Hill affecting the drug industry without the input-some say resistance-of the Pharmaceutical Manufacturers Association."⁷⁰ For Sen. David Pryor, (Democrat-Arkansas) the American drug industry "is more feared than respected by Congress,"⁷¹ and is ranked along with the National Rifle Association and the American Medical Association as the most powerful lobbying organization in the U.S. Industry main lobby group the PMA, operates a few blocks away from the White House in Washington while its counterpart in Canada, the PMAC, locates its offices a few blocks away from Parliament Hill and the Prime Minister's office.

It is estimated that as much as \$31 million U.S. is spent annually to run the PMA in the U.S. According to Drake and Uhlman there is no legislative hearing in the U.S. that has a bearing on the drug industry without the attendance of an official from the PMA. Industry's officials are always armed with the latest industry-

⁶⁹. Roxanne Snider. "Patents and Profits." New Internationalist. August 1993. p-20

⁷⁰. Drake and Uhlman, op.cit. p-40

⁷¹. Novac, op.cit. p-263

generated statistics that disseminate basically the same old argument that their counterparts in Canada similarly use for example that

prescription drugs are cost-effective, account for only 7 percent of medical care costs in this country, and shouldn't come under too much regulation. It costs \$231 million to bring a drug to market, and the industry has to make a sizable profit to reward its investors for taking risks.⁷²

Between 1981 to 1991, according to a study conducted by public advocacy group Common Cause, the industry spent \$8 million through its political action committees on some key members of Congress and Senate⁷³ in exchange for their support for greater international intellectual property rights. This period is perhaps one of the most eventful in the history of the industry as we will see in chapter 3.

Drug companies are known to have friends in the highest places of the American decision making process. The American government with the direct help of President Reagan and Vice-President Bush, later President Bush, and with firm support from key supporters of the industry in Congress and the Senate were able to put pressure on the Canadian government to rescind its drug patent laws in 1987 and 1992. The drug industry boosted some top and most influential figures in American policy making, including George Bush, himself a former employee of the industry.⁷⁴ Reagan's top trade adviser at the time was the Chairman of Pfizer, Edward Pratt,

⁷². Drake and Uhlman, *op.cit.* p-41

⁷³. *ibid.*,

⁷⁴. Snider, *op. cit.* p-20

who spearheaded the industry's campaign within the White House until Canada acceded to the changes demanded by the industry.

Marketing, Advertising and Promotion

The marketing strategy by pharmaceutical companies is yet another contentious issue that has been brought to attention by many critics of the industry. It is essential to make a clear distinction between the production and marketing of pharmaceuticals and those of other products because of their complex healing qualities and serious pharmacological effects. We have already linked the problem of safety of drugs and corrupt practices of the drug industry.

The situations in which patients use drugs can be adequately determined by pharmaceutical manufacturers with sufficient information on side effects, risks and benefits. However, these judgements are not made by the patient but by trained and highly skilled professionals who act as an intermediary between the manufacturers and patients. The fact that it is not the end user that determines the usage and safety of a drug but an intermediary signifies a special relationship between the industry, practitioner and patient. This relationship by and large should adhere to the strictest professional standards under careful state regulatory controls in the best interest of the consumer, but suffice to say this is not so.

The past history of the industry demonstrates little regard for the lives of consumers and the relationship between doctors and patients has always been circumspect. Of great concern to many is the massive sale, promotion and

misleading advertising of psychotropic drugs such as antidepressants and tranquilizers to. Many are led to believe that there is a 'miracle' pill out there for every single conceivable problem they face, from stress, depression, tiredness, sleeplessness, to baldness. Drug companies would like consumers to know that the solutions to these problems are very simple, 'just simply pop a pill and forget your worries.'

The application of scientific and technical expertise in the development of psychotropic drugs as 'cures for all problems', can be described as an attempt to make innocent humans feel that

human behaviour, and a growing range of social deviance, is best accounted for in terms of the biological fundamentals of cellular and molecular functioning. Allied to this is a perception of the human body -including the mind-as a machine with relatively interchangeable and standardized components that are responsive to intervention.⁷⁵

The introduction of psychotropic drugs has its origins during the 1920's and 30's when drug companies promoted cocaine-laced capsules and heroin-based products as a form of drug therapy for the sick. Most importantly the success of the sale of these products encouraged the development of tranquilizers and antidepressants for legitimate consumption. Significantly their introduction into the market paved the way for the transformation of pharmaceuticals "into areas of social intervention and

⁷⁵. Peter Davis. "Pharmaceutical and Public Policy." in For Health or Profit, ed by Peter Davis. (Auckland, Melbourne and New York: Oxford University Press, 1992) p-7 and 8.

behaviour modification,"⁷⁶ which "subtly transforms social 'problems' into individual and personal 'solutions'."⁷⁷

Sales for these types of drugs such as Valium, prosac, sleeping gels etc., are heavily promoted through visits by promotional agents of pharmaceutical companies to doctors. The sale for example of Valium in the United States has accounted for 33 million prescriptions being filled at cost of \$293 million for the year 1980.⁷⁸ Promotional campaigns by drug companies are deliberate and misleading to doctors who become victims of a conspiracy to deceive patients about the therapeutic value of drugs for the sake of profits.

The following quotation from an American subsidiary based in Canada, Mead Johnson, proves to what extent drug companies would go to mislead patients and yet confirm their actions.

By means of overwhelming promotional techniques the public has been made to believe that drugs such as sedatives, narcotics, antipyretics, skeletal muscle relaxants, anti-spasmadoics, etc. possess unique tranquilizing activities. These drugs do indeed posses unique pharmacological activities but tranquillization is not one such activity.⁷⁹

This deception is hardly an accident but yet another deliberate ploy which is

⁷⁶. Davis. op.cit. p-7 and 8

⁷⁷. *ibid.*,

⁷⁸. Clinard and Yeager, op.cit. p-58

⁷⁹. quoted by Hon. William D. Howe (Hamilton South) in House of Commons Debates. February 12, 1968. p-6643

consistently being used to deceive consumers.

Pharmaceutical corporations in Canada are known to spend as much as 30 cents out of every dollar in advertising on promotion to doctors. Fortune magazine points out that the brand name industry spends twice as much on sales and marketing as it does on research and development.⁸⁰ Besides the glossy colourful journals and magazines written by company executives that are distributed free to doctors, drug companies organize "continuing education" seminars in out of town locations with all expenses paid as a way of marketing their products. Some doctors are given promotional gifts such as computers and expense free vacations depending on how much brand name drugs they prescribe. In 1989 Squib Canada gave computers to doctors who prescribe its drug Capoten to 10 or more patients.⁸¹ Each year multinational drug companies spend "over \$750 million a year on lobbying, advertising and promotions to influence the kind of treatment you receive [while] they spend \$385 million on research."⁸² Allegedly the process of deceiving patients starts from medical schools where interns are taught only a basic course in pharmacology. Therefore they are likely to be influenced by drug companies who distribute "textbooks with lustrous graphics and a free stethoscope"⁸³ to all students.

⁸⁰. Maude Barlow and Bruce Campbell. Take back the Nation (Toronto:Key Porter Books Ltd, 1993.) p-107

⁸¹. Toronto Star. "Drug firms spend lavishly to push products." September 4, 1993. p-B5.

⁸². *ibid.*,

⁸³. *ibid.*,

Against this background, access to drugs and medical treatment should be based on "social judgements of benefit-improvements in health-rather than just intrinsic profitability."⁸⁴ Given the role of the state in the provision of free health care, greater control and regulation is required to make sure that the drug industry is responsive and responsible to the needs of the public. The practice of spending huge sums of money on promotional campaigns to gain brand name loyalty compromises the safety of consumers and contributes to the high cost of medicines. Oligopoly within the industry, therefore, should not be perpetuated by fostering dependence of members of the medical community on information provided by the drug industry, rather the supply of cheaper brands of medicines through generic competition should be the alternative.

Conclusion

The development of a state public policy on the pharmaceutical industry should not be considered in isolation from the issues raised during this chapter. An analysis on the merits of greater intellectual property protection and its dire financial consequences for health care, the sick and needy is only one aspect of the argument. The other is the industry's role in the provision of medical care to the community. Yet it seems from the industry's perspective that the only issue of concern to it is the fight for greater intellectual property protection through state protection from

⁸⁴. Davis, op. cit. p-2 and 3

competition. The industry has skilfully managed to deflect the concerns and issues raised in this chapter throughout the debate on Bill C-91 because of the intransigence of policy makers, the media and the facilitatory role and support by the state.

Chapter 2

Theoretical analysis of State, Public Policy and Dependency Theory

General Introduction

The state in contemporary society and public policy is the focus of fierce debate and analysis that varies according to one's political and ideological beliefs. It is one of the most complex and pervasive institution of our times since it affects the interests of many people as a result of one's social, political, economic and class background. The state according to Ralph Miliband is a system of institutions -- the government, the bureaucracy, the military, police, the judiciary, sub-central government and parliamentary assemblies.¹ Some liberal theorists also interpret the state as an institution organised with the goal of reconciling and mediating inherent antagonisms among various groups. The functions of these institutions and their interrelationship form the basis of the state system. In order to facilitate a clear understanding of the role of the state in public policy it is necessary to examine the relation between the political and state system.

Since, as Miliband indicates, the state is a system of institutions, an analysis of the distribution of power and its relationship between individuals and institutions is important. Power is defined as the authority and capability to make decisions by institutions and individuals that affect the lives of others through the ability of

¹. Ralph Miliband The State in Capitalist Society. (London: Quartet Books, 1973) p. 46-

putting these decisions into effect. This is also a crucial element of understanding the political and state systems. The political system includes political parties, trade unions, associations, interest groups and also non- political organizations that are very influential, such as the media, churches and business.² These institutions wield considerable power, authority and influence within the state and the policy process to satisfy their own interests.

Whatever the state does, it is individuals who are most affected by its actions. The prevalence of the state represents the pivot of political organizations of society where every aspect of human life from birth to death is regulated and controlled to some extent.³ The rampant growth of state intervention and regulatory control over humans contribute to the strengthening of power and authority of the state. Failing to come to grips with the state and to obey its laws would be a threat to the state itself and to the existence of power and authority of its institutions. The state therefore to exist, as Weber stated, must "successfully claim the monopoly of the legitimate use of physical force within a given territory."⁴ Which other institution can be called upon to realize this task, other than the police and military in the preservation of law, order and peace? The state exercises authority and power which tends to

². *ibid.*, p-47

³. Christopher Ham and Michael Hill. Policy Process in the Modern Capitalist State. (New York: St. Martin Press, 1984) p-23.

⁴. Miliband, *op. cit.* p-47.

isolate it from the people. It also uses less authoritative means through coercion, exhortation and threats to secure compliance with its demands.

Ideological Perspectives of the State.

Another important aspect of the state is the role it plays in the production of ideology in modern day society. The term "ideology" is often confused and misunderstood in terms of what it is or what it is not. The lack of appreciation of its importance can severely restrict our ability to analyze and comprehend the role of the state in the policy process. Defining this problem is no guarantee that we can solve it, given the inherent class structure, divergent interests, power and influence of various social groups. Ideology represents a totality of ideas, assumptions, beliefs, explanations, values and opinions on how we are supposed to perceive our social-natural relations and environment. This will no doubt have an impact on our perception of politics and the role of the state. Obviously, political science is not only the empirical study of the distribution of power in society; it is concerned with the practical involvement in conflicting social institutions. It is important to understand that this correlation not only affects the structure of the state but also the activities of the political and state systems in the final determination of public policy.

In this context we understand ideology, in the sense used by Marx, as the rationalization of economic exploitation, political domination, social discrimination and human alienation and, as an inaccurate, out-of-focus, inadequate superstructural

reflection of world capitalist material production, economic relations and forces of production.⁵ According to Marx, state ideology deliberately distorts reality to serve dominant class interests in public policy. The role of ideology, but more importantly political ideology, is significant in understanding the content and direction of the political and economic policy of the state and its institution as well as the political behaviour of the masses. Political ideology therefore can be understood as a system of beliefs about what role the state should play in society as perceived by some class or group.⁶

A particular ideological perspective is the result of an elusive and almost impenetrable process of political socialization in the interest of the status quo or dominant class. The agents of this process are the government, political parties, the media, the educational system, for example, schools and universities, the family, peers and the workplace. They help to pattern and shape policy in the interests of the dominant ideology that seeks to maintain the dominant role of existing institutions.

Theories of the State.

As stated before, the state is the focus of a continuing debate and analysis as to its character, role and purpose in a capitalist society. Ralph Miliband describes

⁵. Franz J.T. Lee Theoria-Praxis de la Revolucion-Emancipacion. (Merida: CDCHT/Facultad Forestal, Universidad de los Andes, 1989) p-86

⁶. A. P Sheptulin Marxists Leninist Philosophy. (Moscow: Progress Publishers, 1980) pp.420-424.

the theory of the state as a "theory of society and the distribution of power in that society."⁷ An analysis of the distribution of power in society is fundamental to understanding of the role of the state in policy-making. Many theoretical perspectives have been outlined from time to time on the role and function of the state in policy-making and ultimately why and who benefits? Of particular importance to our analysis of Canadian public policy are the Pluralist, Marxist and Elite theories.

Pluralist Theory Of The State.

Pluralism is based on the idea that the nature and distribution of state power is dispersed and divided into a number of groups rather than centralized. The pluralist theory views the state as an 'honest broker' that serves as a neutral body to make decisions in the best interests of all groups of society. However, according to Alford and Friedland, rarely is the expression "state" used by pluralist theorists, instead, many prefer to use terms such as "political system," (Easton 1965) "political community," (De Grazia 1948) "polity," (Long 1962) or "pluralist system." (McFarland 1969)⁸ This preference is based on the premise that suggests diverse sources of authority within the state, based on open and accessible government institutions. The interests of state institutions are fragmented and are often

⁷. Miliband. op.cit. p. 4-5

⁸. Robert Alford and Roger Friedland Powers of Theory, Capitalism, the State and Democracy. (London: Cambridge University Press, 1986) p-41

positioned against one another; therefore little attention is placed on the role of the state and more on the political system which is regarded as the source of competition among interest groups.

The primary function of the state according to pluralism is to serve as a neutral arbitrator to aggregate choices and to integrate differing opinions to build consensus and compromises in the policy process. Pluralists have argued that the nature and development of modern industrial societies have contributed to the specialization and differentiation of new occupations, professions and groups with a particular interest to protect and promote. As a result different groups and organisations are formed to articulate and represent their specific concerns, needs and interests within the policy process. These groups are known as interest groups. The notion is that there is strength in numbers and those who join together can apply pressure on the decision makers or the public as a whole to reach decisions that are in their interests. Pluralism, therefore, argues that the modern state is a system of power designed to encourage competition within the policy process through bargaining and compromise among various groups.

The assumption therefore of the pluralist theory is that groups are formed to influence the state, but this says nothing about their effectiveness in representing their members. Not all groups possess the same economic power and resources to influence government and therefore some are excluded from the decision making process. Moreover some individuals do not belong to groups hence they too are

excluded. This means that decisions are made without the full participation and input of all. E.E. Schattschneider notes in a popularly cited passage that, "The flaw in the pluralist heaven is that the heavenly chorus sings with a strong upper class accent."⁹ This upper class accent can be attributed to the huge financial resources possessed by certain groups, especially business, for example the Business Council on National Issues, the Canadian Chamber of Commerce, the Canadian Manufacturers Association and the Pharmaceutical Manufacturers Association of Canada. These resources can be used to hire lawyers, public relation experts, public policy specialists and lobbyists to represent their interests not only to the state but to the public.

Here in Canada the basic source of power which serves as a breeding nest for influencing policy is between the political executive, (cabinet and the bureaucracy) since Parliament is closely controlled by the government in power and political parties. Nevertheless the implication of the pluralist approach to policy making is that the state is basically democratic and all interests are equally represented through the policy process.

Joseph Schumpeter in his book Capitalism, Socialism and Democracy¹⁰ sees the goals for political office as a competition between elites for the votes of the

⁹ E. E. Schattschneider The Semisovereign People (Hisdale, Illinois: The Dryden Press, 1960) p. 34-35

¹⁰ Joseph Schumpeter Capitalism, Socialism and Democracy. (New York: Harper & Brothers, 1943)

masses. This scenario operates within the ambit of a market where the voters are perceived to be like consumers who have the option of choosing the best policies [products] among the competing political parties [sellers]. The significance of this analysis is that the policy-making process within government is dominated by competing elites who to some extent have to be responsive to popular demands or risk being replaced by other competing elites. Therefore in Raymond Aron's words "government becomes a business of compromise."¹¹

But even according to Dahl, a noted defender of pluralism, the making of government decisions "is the steady appeasement of relatively small groups. Even when these groups add up to a numerical majority at election time it is usually not useful to construe that majority as more than an arithmetic expression."¹² A good example in point is that despite the overwhelming reaction and evidence against Bill C-91, the Conservative government still maintained that it was in the best interests of all Canadians to pass the legislation.

This action amply explains the role of the state in the policy process which, according to many, favours the interests of business. Charles Lindblom, for example in his work Politics and Markets,¹³ acknowledges that because of greater economic

¹¹. Raymond Aron "Social Class, Political Class", in Bendix and Lipset, ed. Class, Status and Power. 2nd ed. (London: Routledge Kegan Paul, 1967) p-208

¹². Robert Dahl A Preface to Democratic Theory. (Chicago: University of Chicago Press, 1950) p-234

¹³. Charles Lindblom Politics and Markets. (New York: Basic Books, 1977)

resources and lobbying ability the interests of business are given a "privileged position," in the policy process. According to him, large corporations "command more resources than do most government units. They can also, over a broad range, insist that government meet their demands, even if these demands run counter to those of citizens expressed through their polyarchal controls."¹⁴ William Coleman in his book Business and Politics notes that the notion of pluralism "distorts and hides what actually occurs in practise." According to him, "There is a systematic bias in the Canadian system, which consistently gives the business community a better hearing and considers its demands and proposals more seriously when policies are being designed."¹⁵ Theodore Lowi offers a different perspective by noting that the policy process is "biased not so much in favour of the rich as in favour of the established and organised."¹⁶ But he also recognises that the interests of business dominate the policy process since it is in the mutual interests of the state and business to have stability that would facilitate their performance. Despite this recognition by some analysts of the political power of big business, the pluralist belief is in sharp contrast to the Marxist analysis which suggests that society is an inevitable product of an antagonistic class division, based on historic social, political

¹⁴. *ibid.*, p-356

¹⁵. William Coleman Business and Politics: A study of Collective Action (Montreal: McGill- Queen's University Press, 1988) p-3

¹⁶. Theodore Lowi The End of Liberalism. (New York: W.W. Norton, 1979) p-280

and economic exploitation. According to Marxists, this division is held in check by an authoritative hegemonic state that facilitates its survival through coercion and consent.

Marxist theory of the state.

According to Marxian analysis, the state is not an "honest broker" or a neutral body that makes decisions for the benefit of all, rather it is an instrument of class domination. In the Communist Manifesto, Marx wrote "The executive of the modern state is but a committee for managing the common affairs of the whole bourgeoisie."¹⁷ This statement by Marx can be appreciated from an analysis of the economic, social and political functions of the modern class state.

The essence of Marxian theory roots itself in the relationship between the owners of the means of production and the producers of wealth, the workers. The workers are forced to sell their labour power at a cost determined by the capitalist and not by how much the worker feels he or she is worth. This unequal relationship provides the basis for political antagonism between the social classes and the foundations for the existence of the capitalist state. The purpose of the state is therefore to defend and protect the interests of the owners of private property (dominant classes) vis-a-vis the workers (the dominated classes). The existence of private property has shaped the role and function of the state and without its

¹⁷. Karl Marx and Freidrich Engels The Communist Manifesto. (New York: Appleton-Century-Crofts, 1950) p-20

existence the fundamental base of the state will be radically changed.

According to Marx and Engels, the primary political purpose of the state is to serve the needs of the dominant class. The political structure, the state, is designed to organize the necessary conditions for economic exploitation and political domination backed by a coercive apparatus. The state helps to mediate class conflicts; it has a social function in so far as it fosters an ideology to rationalize and veil its real political and economic functions. Generally this ideological function is materialized within the framework of the intellectual production of social norms and behaviour patterns for example within the ambit of schools, universities, the mass media, but also through religious bodies, especially the church, to encourage docility and obedience through consent and coercion. The state socially nurtures discrimination against the dominated classes for example by applying its own principle of "divide and rule." The state, through policies, programs and projects forces the dominated classes to affirm the ruling class structure, the status quo, so as to get the dominated classes to forget their own class demands and interests.¹⁸

After Marx, a number of Marxist theorists have also helped to develop a Marxian theory of the state. Ralph Miliband in The State in Capitalists Society¹⁹ has demonstrated evidence of a linkage between business and the state and how much business has benefited from state intervention in the economy through formation of

¹⁸. Lee, op.cit. Chapter 3-5

¹⁹. Miliband, op.cit.

the Welfare State. According to him the state is simply an instrument of class rule, which continually facilitates the centralization and concentration of capital and as a result the concentration of power within the capitalist society in the hands of a few. Miliband also shows the effects of the ideological congruence of elements of the government, administration, military, judiciary and other agencies in alliance with businesses. Nicos Poulantzas, described as a structuralist critic, differed from Miliband's analysis of the state. According to him the state still has considerable autonomy from the business class and as a result is able to quell rivalries and conflicts within the capitalist class. Personal ties and ideological congruence may be coincidental and do not matter much.²⁰

James O'Connor also offers another approach to the study of Marxian theory of the state. In his analysis of The Fiscal Crisis of the State,²¹ he describes what he sees as the main functions of a capitalist state, namely accumulation and legitimation. According to him, the dominant class depends on the state to create the conditions for the accumulation of capital by investing in the building of the economic infrastructure. O'Connor feels that the legitimizing function of the state is necessary in order to preserve social harmony in the midst of deep-rooted class antagonism and conflicts. The state must demonstrate its legitimacy to the working class by appearing to take an interest in their problems by investing in social

²⁰. Nicos Poulantzas Political Power and Social Class. (London: Verso Publications, 1973)

²¹. James O'Connor The Fiscal Crisis of the State. (New York: St. Martin Press, 1973)

expenditures and social welfare.

Elitist Theory of State.

Central to the elite theory of the state is the argument that a small minority has the power, influence and authority to bar the rest of the population from access to the decision-making process. However, elitists do not believe that political power is necessarily based on control of the economy, although it may be. Elite is a political nomenclature that differs from the Marxists economic term 'class' and also challenges the pluralist analysis that power is dispersed among a large segment of the population.

A number of classical elite theorists such as Mosca and Pareto have concluded that it is inevitable for state power to be dominated by a small minority. They also argue that it is natural and necessary for there to be a 'power elite' in any society given the fact that any group that attains political power would inevitably try to consolidate its own power base and privileges. Mosca for example states

In all societies -- from societies that are meagrely developed and have barely attained the drawings of civilization, down to the most advanced and powerful societies--two classes of people appear-- a class that rules and a class that is ruled. The first class, always the less numerous, performs all political functions, monopolises power and enjoys the advantages that power brings, whereas the second, the more numerous class, is directed and controlled by the first, in a manner that is now more or less legal, now more or less arbitrary and violent.²²

For Pareto, society is also made up of two classes of people, they are 1. "the lower

²². Gaetano Mosca The Ruling Class (New York: McGraw-Hill, 1939) p-50

stratum, the non elite... and 2. the upper stratum, the elite class."²³ Inevitably the upper stratum will be the rulers of society because of superior education, intellect and biological abilities.

In the post-second World War period, C. Wright Mills in a study of the United States, concluded that the most influential decision makers in the American political system are made up of the very top echelons of society. They display the same social and educational backgrounds and are often biologically linked to one another. They also occupy the most important positions in government, business and the military and are able to manipulate and control the masses for their own interests. Leaders of these institutions, because of their link to one another, are able to create a coherent power elite to protect their interests.²⁴

Modern day elite analysis draws a special link between the state and business elites. The state elites are dependent on the business elites for their survival in financial support through taxes, job creation and investments. A failure of the economy will undermine the ability of the state to survive economically. Although studies by Porter and Clement have concluded that there are competition and some differentiation among state and business elites in Canada, they have also indicated that elites are all disproportionately recruited from the upper class and share the

²³. Vilfredo Pareto Sociological Writings (Oxford: Basil Blackwell, 1976) p. 248-249

²⁴. C. Wright Mills The Power Elite (New York: Oxford University Press, 1950)

same set of biases in making decisions in their favour.²⁵ Elites, therefore, are the crucial gatekeepers of society who exercise control, power and influence over the political and state system. Subsequently other studies by Robert Presthus and Jorge Niosi have focused their attention on the social and ethnic background of state and business elites.²⁶ They arrived at similar findings to that of Porter and Clement which demonstrate a great sympathy for the upper class in the decision making process. These findings are significant in understanding the nature of democracy and policy making in Canada.

Given our analysis of the theories of the state we would now attempt to analyze the role of the Canadian state and public policy. We would also examine the merits of the Dependency Theory and its impact on Canadian/American relations and public policy.

Canadian State and Public Policy

Throughout the historic economic evolution of Canada, the state has been an active participant in promoting the development of capitalist relations of production. The National Policy, for example, was an explicit attempt to facilitate the interests of the capitalist class in Canada. Reg Whitaker describes it as

²⁵. John Porter The Vertical Mosaic: An Analysis of Social Class and Power in Canada (Toronto: University of Toronto Press, 1968) and Wallace Clement Canadian Corporate Elite: An Analysis of Economic Power. (Toronto: McClelland and Stewart, 1975)

²⁶. Robert Presthus Elite Accommodation in Canadian Politics (Toronto: MacMillian Canada, 1977) and Jorge Niosi Canadian Capitalism: A Study of Power in Canadian Business Establishment (Toronto: J.Lorimer, 1981)

a protectionist national development plan which saw the sponsorship of an east-west economy linked by a national railway, industrialization being protected by tariffs, with a captive market in the Western prairie hinterland which would provide foreign exchange through wheat exports.²⁷

According to Paul Phillips the major beneficiary of this policy was Central Canadian capital whose financial interest were so paramount that "even without the goal of capturing a western frontier the pressure for adopting a protective system would probably have mounted."²⁸

Brooks and Stritch argue that prior to the 1878 national election the issue of laissez-faire versus protectionism was high on the agenda for the business community.²⁹ Most members of the business community in Central Canada were vehement in arguing for state support and interference in the market and in favour of protectionism. The Conservative party led by John A. Macdonald championed the business initiative during the elections and promptly introduced protectionism after winning the elections. The intention was the creation of an industrial base in Ontario and Quebec under protection from American intrusion and competition which it did "until American capital movements made the tariffs ineffectual as a national

²⁷. Reg Whitaker "Images of the State in Canada in Canada", in The Canadian State, Political Economy and Political Power. Ed, Panitch, Leo. (Toronto: University of Toronto Press, 1977) p-45

²⁸. Paul Philips "The National Policy", Journal of Canadian Studies. Volume 14, No.3, 1979. p-5

²⁹. Stephen Brooks and Andrew Stritch Business and Government in Canada (Toronto: Prentice-Hall Canada, Inc. 1991) p-37

strategy."³⁰

Jackson and Jackson note that the National Policy "represented the first major incursion of the state into economic life in Canada."³¹ But perhaps the unintended effect of this policy was the rapid domination of the Canadian economy by American branch plants so much so that Donald Creighton laments that

since the Second World War, while Canadians have been steadily selling their birthright in order to live in affluence, Canada has taken on more and more the characteristic of a branch plant economy.³²

Roger Gibbins felt that the National Policy was intended "as a barrier to goods rather than to capital, it was not designed to keep out American investment,"³³ thus the eventual domination of the Canadian economy from capital by the U.S. was inevitable. By 1960, as Garth Stevenson noted

American interests controlled 44 percent of the capital invested in Canadian manufacturing, 64 in petroleum, 53 percent in mining and smelting, while the percentage of capital under Canadian control in these three sectors of the economy had fallen to 41, 27, and 39 percent, respectively.³⁴

³⁰. Philips, op. cit. p-5.

³¹. Robert Jackson and Doreen Jackson Politics in Canada: Culture, Institutions, Behaviour and Public Policy (Toronto: Prentice-Hall Canada, 1990) p-62

³². quoted in Gibbins, Roger. Conflict and Unity, An Introduction to Canadian Political Life (Toronto: Metheun Publications, 1985) p-187. Original in Donald Creighton The Passionate Observer: Selected Writings (Toronto: McClelland and Stewart, 1980) p-45

³³. Gibbins, op. cit. p-186

³⁴. Garth Stevenson "Federalism and the Political Economy of the Canadian State." in Panitch, op.cit. p-84

This historic interventionist role of the Canadian state in favour of the interests of business clearly served as a severe affront against the principles of "laissez-faire" as espoused by the representatives of conservatism and classical liberalism, a trend that will continue to the 1990's. The idea of "laissez-faire" is based on a basic postulate, namely the efficiency and effectiveness of the private market as compared with government intervention in the economy. "Laissez-faire," is also "a doctrine that includes a belief in the private ownership of property, in the rights of individuals to dispose of their property as they so choose, and in the superiority of the free market as a means for promoting the well-being of individuals and society as a whole."³⁵ Yet, as a result of the National Policy there was a rejection of free trade guided by market principles and the concept of classical political economy ³⁶ in preference for what John A. Macdonald calls the best interest of "our national prosperity."³⁷

An important contributory factor to the development of the Canadian state, and of its interventionist role in favour of business and regions in public policy, was from its federal structure. The establishment of Confederation was arguably as a result of an attempt of the founders to preserve the power and authority of the emerging economic class of society namely the industrial capitalists and the new

³⁵. Brooks and Stritch. op.cit. p-28

³⁶. Whitaker, op. cit, p-46.

³⁷. Brooks and Stritch, op. cit. p-38

emerging "important property owning class" of farmers.³⁸ The division of powers between the federal and provincial governments was therefore linked within the vision of creating a state as envisaged by the Fathers of Confederation but with power and authority to realize the dreams of the National Policy. With reason therefore, the most important function of the state and public policy were in the realm of its economic role which was "represented by jurisdiction over railways, shipping, money and banking, the tariff, and major public works were retained in Ottawa."³⁹ The provinces assumed the responsibility for health, education and welfare.

One aspect of the economic function of the Canadian state is its role in the provision of the basic conditions of production which cannot be guaranteed by members of the private sector. Since the latter part of the nineteenth century, the role of the state has increased from the provision of defence, trade, foreign policy and the management of currency to the building of basic infrastructures for private sector economic development such as roads, railways, bridges, airports, waterways, and canals.⁴⁰ The state also provided favourable fiscal and monetary support for the private sector through capital and financial backing to businessmen. According to

³⁸. Stevenson, op.cit, p-74

³⁹. ibid., p-75.

⁴⁰. Janine Brodie and Jane Jenson Crisis, Challenge and Change (Toronto: Methuen Publications, 1980) p-22

Panitch it has "underwritten the private risks of production at public expense through grants, subsidies, fast write-off depreciation allowances, etc."⁴¹ However at the same time according to Moscovitch and Drover "neither economic and social conditions, the nascent working and professional classes, nor the early social reform movements demanded or required significant state intervention for the provision of social welfare."⁴² Perhaps this can be attributed, as Jackson and Jackson have indicated, to "the delayed nature of Canada's industrial revolution; to the weakness of the working class as an organised political force; to the strength of the business community in restricting the role of the state to promotion and protection of its own interests."⁴³ The obvious beneficiaries of state action in the economy were the dominant and business classes in Canada.

Compared to the state's involvement in the economy on behalf of business, the state's role in the development of social policies came relatively late and only after a series of struggles against labour. With the growth of industrialization, workers increasingly developed a level of class consciousness, encouraged by social ferment through strikes, lockouts and protests for better working and living conditions. The state, despite increasing advocacy and strength from trade unions,

⁴¹. Leo Panitch "The Role and Nature of the State." in Panitch, op. cit. p-14

⁴². Allan Moscovitch and Glenn Drover "Social Expenditures and the Welfare State: The Canadian Experience in Historical Perspective", in Allan Moscovitch and Jim Albert. (ed) The Benevolent State (Toronto: Garamond Press, 1987) p-17

⁴³. Jackson and Jackson, op.cit, p-63

social reformers and the women's movement, consistently resisted attempts to pursue social policies for the betterment of workers. Coercive measures were often used to keep the economic system going, by using the military to repress strikes and demonstrations, deportations of progressive leaders and sympathizers of movements and the banning of organisations.⁴⁴

It was not until continuing struggle and increasing class antagonism between labour and capital took place that gradual changes were made. The effects also of the depression and Second World War forced the state into an effort to defuse social tensions. The state introduced wage freeze and price controls on goods and rent. It also established crown corporations that were essential to the war-time effort. This new intervention in the economy after 1940 but with the continued dominance of the market has sometimes been attributed to the influence of Keynesianism. It was argued that Keynes offered a solution to the economic crisis of the 1930's and provided the basis for government to "construct both a permanent infrastructure of programs that would stabilize the economy ... and also strategically alter aggregate taxing and spending activities to ensure that economic investment and consumer demand was maintained."⁴⁵ State intervention in the economy, as we already noted, took place from the inception of the National Policy but with the advent of the

⁴⁴. Moscovitch and Drover, op. cit, p-27

⁴⁵. Bruce Doern and Richard Phidd Canadian Public Policy (Toronto: Nelson Canada, 1992) p-137

depression the role of the state changed by assuming the responsibility to maintain aggregate demand thus, eliminating the "need for concern over the organisation of production and supply."⁴⁶ It is arguable however, whether Keynesian economics was ever fully practised here in Canada. According to Doern and Phidd the post world war period of Canada's economic development was undertaken by the Department of Reconstruction and Defence Production, and later by Trade and Commerce headed by C.D. Howe. Howe used "tariff and tax policies to encourage foreign equity investment in Canada,"⁴⁷ which continued the spirit of the National Policy of reinforcing a branch plant economy.

However, only gradual changes were made over a period of time. The Workers Compensation Act was introduced in 1920 followed by Old Age Pension in 1927. But, since the Second World War "health care plans and hospital insurance, the Canada and Quebec Pension Plans, housing policies, grants for higher education and guaranteed income supplements"⁴⁸ were introduced. This new relation or function of the state is described by James O'Connor as the legitimizing role where conditions dictate greater social intervention and spending on social programs, to protect the economic climate for business by assuming the social cost of

⁴⁶. John Shields and Stephen McBride Dismantling a Nation (Halifax: Fernwood Publishing, 1993) p-49

⁴⁷. Doern and Phidd, op. cit, p-138

⁴⁸. Jackson and Jackson, op. cit, p-62

production.⁴⁹ However, according to Stephen Brooks the differences between state intervention and interference in markets and in social policy is that

the immediate beneficiaries of state intervention are different in the two cases [families and individuals versus producers] and the welfare state usually is associated with society's less-privileged elements... In both cases state intervention has the effect of insulating some part of society from the unregulated workings of the market.⁵⁰

The state's interventionist role in the economy was widely accepted by the Canadian dominant class without much opposition, primarily because it not only nurtured the stability of capitalism but must preserve and "sustain a capitalism with international and multinational connections," to their benefit.⁵¹

The introduction of a 'Keynesian' approach to management of the Canadian economy contributed to its growing continental integration through expanded economic ties with the United States. In the process the Canadian ruling class became more integrated with the American. This explains the greater influence in policy making on behalf of American multinationals in order to maintain their position "as a supplier of services to both national and multinational corporations."⁵² According to Garth Stevenson it would be "more useful to think in terms of a North

⁴⁹. O'Connor, op.cit.

⁵⁰. Stephen Brooks Public Policy in Canada (Toronto: McClelland and Stewart Inc, 1990)

⁵¹. Brodie and Jenson, op. cit. p-220

⁵². *ibid.*,

American economy than of a Canadian economy,"⁵³ because of the close proximity and economic power and influence of the U.S. Since 1945 well over 70 percent of foreign capital invested in Canada came from the U.S, in addition to an almost equally large proportion of U.S.- Canadian foreign trade.⁵⁴ American ownership of the manufacturing sector grew from 35 percent in 1946 to an unprecedented 60 percent in 1963.⁵⁵

Dependency Theory and Canadian/American Relations.

George Grant, in his book Lament for a Nation, attributed the American domination of Canada to the actions of Canadians themselves. According to him

after 1940 it was not in the interests of the economically powerful to be nationalists. Most of them made more money by being the representatives of American capitalism and setting up the branch plants. No class in Canada more welcomed American managers than the established wealthy of Montreal and Toronto,⁵⁶

and as a result, the roots of continental integration were established.

American dominance of the Canadian economy is far greater in comparison to other developed countries. This has contributed to the integration and dependence of Canada on the U.S economy which can be characterized as a state of economic

⁵³. Garth Stevenson Unfulfilled Union (3rd edition, Toronto: Gage Educational Publishing Company, 1989) p-179

⁵⁴. Van Gerry Houten Corporate Monopoly (Toronto: Progress Books, 1991) p-119

⁵⁵. Brodie and Jenson, op. cit. p-218

⁵⁶. George Grant Lament for a Nation: The Defeat of Canadian Nationalism (Toronto: McClelland and Stewart, 1965) p-47

colonialism. U.S domination has in the process "distorted and retarded Canada's industrial development and made Canada vulnerable to U.S. economic and political pressure,"⁵⁷ a factor that was visible in Canada's defence of American multinationals in pursuing greater intellectual property rights through GATT and NAFTA. The American dominance is the source of a great debate among many Canadian political economists and academics. The central question is to what extent Canada's dependency on U.S. capital for its technological and economic development contributed to its subservience to American political power in the decision-making process?

A popular explanation of this situation is the "dependency theory" approach which argues that despite Canada's political sovereignty, its economic development has been retarded because it is too clearly tied to the United States for its industrial economic development. As a result, Canada is in a position of dependency vis-a-vis the U.S. and other metropolitan countries. This approach more or less explains why Canada failed to develop independently an industrial economy free from foreign dominance. The "dependency theory" inherits its theoretical base from the "staples thesis" of Harold Innis and others who argued that Canada's dependence on the export of staples benefited other industrialized countries while retarding its industrial and technological progress because of the time and money spent to

⁵⁷. Houten, op. cit. p-119

develop the infrastructure to support a staple economy.⁵⁸

A review of some of the works of Canadian political economists and academics would perhaps help to determine the validity of this dependency on the U.S. and its impact on Canadian public policy in relation to American political and economic influence. Wallace Clement in his book Continental Corporate Power, argues that as a result of a historic alliance between American and Canadian capitalists over the past century both have managed to reinforce their power and influence in the decision-making process to their mutual advantage. Clement views this relationship as an unequal alliance with American dominance of the productive sector in Canada with Canadian capitalists relegated to the role of servicing and expanding the economy in the interests of American capital.⁵⁹ This unequal relationship between the two has resulted in the development of a continental elite with an objective to protect its own interests. According to him, "Canada cannot be characterized as an advanced independent capitalist society, nor can it be grouped with the various peripheral nations often called "the Third World," although it shares some traits with each type."⁶⁰

Mel Watkins builds his analysis on Canadian political economy on the basis

⁵⁸. For more on the "Staple approach" on the Canadian economy see, Harold Innis The Political Economy of the Modern State (Toronto: Ryerson, 1946) Harold Innis et. al. Problems of staple Production in Canada (Toronto: Ryerson, 1933)

⁵⁹. Wallace Clement Continental Corporate Power (Toronto: McClelland and Stewart, 1977) p-6

⁶⁰. *ibid.*, p-7

of the Innisian staples approach. According to him Canada's past dependence on staples led to the nourishing of an "export mentality, resulting in an over-concentration of resources in the export sector and a reluctance to promote domestic development."⁶¹ As a result Canadians became dependent on nations that receive its exports and those that supply it with manufactured goods. Watkins contends that Canada's economy is "staple-biased; the industrial structure is truncated and dependent; the Canadian bourgeoisie is continentalist to the core; the society is pervasively Americanized," and as a result Canada's economic development is constrained to the benefit of the Americans.⁶²

Kari Levitt in her book Silent Surrender described Canada as the "world's richest underdeveloped country," thanks to the role of Canadian entrepreneurs whom she depicts as the "coupon clippers and hired vice-presidents of [American] branch plants today."⁶³ According to her, American multinational domination of the Canadian economy restricts the autonomy of the Canadian state since American businesses are not only able to make profits from their investments in Canada but also to reinvest them to take control of the economy and reinforce Canadian dependence on American technology. Therefore, "the greater the degree of foreign

⁶¹. Mel Watkins "A Staple Theory of Economic Growth." Canadian Journal of Economics and Political Science Vol. 29: 1963. p-63

⁶². Mel Watkins "The Political Economy of Growth", in Wallace, Clement and Williams Glen, ed. The New Canadian Political Economy (Montreal: McGill-Queen's University Press, 1989) p-31

⁶³. Kari Levitt Silent Surrender (Toronto: Macmillan, 1970) p-40

ownership and control of Canadian industry, the narrower the freedom of choice in economic as well as political matters."⁶⁴ Daniel Drache views Canadian industrial dependence on the U.S. as a consequence of the "capitalists mode of production"⁶⁵ and its past reliance on the staple economy. As a result, Canada's industrial development has been incomplete. Thus, Canada is caught between two camps of the world economy: "under-industrialized by imperial interests, but not completely dependent and sharing many of the social relationships of advanced capitalism."⁶⁶ Nevertheless, he predicts the eventual collapse of the Canadian economy with its status being reduced from a "semi-centre economy to a semi-peripheral one."⁶⁷

Conclusion:

The dependency approach embraced by a number of Canadian academics in explaining U.S. dominance of the Canadian economy adopts a position based primarily on nationalistic concerns and on economic disadvantages Canada faces as a consequence of past domestic policies. It also highlights concerns about the role of the Canadian state and its business elites in the nation's industrial development. One can therefore arrive at the following conclusions: Canadian dependency on the U.S.

⁶⁴. *ibid.*, p-9

⁶⁵. Daniel Drache "Staple-ization: A Theory of Canadian Capitalist Development", in Heron, Craig, ed. Imperialism, Nationalism and Canada (Toronto: New Hogtown Press, 1977) p-16

⁶⁶. *ibid.*,

⁶⁷. quoted in Glen Williams "Canada in the International Political Economy", in Clement and Williams. ed, op. cit. p-123

is a social, political and economic problem which is reflected in the Canadian policy process vis-a-vis the U.S. as a consequence of a disparity of power and social classes between the two countries. It can also be seen as a more complicated sophisticated process of domination deliberately established by the economic elites of both countries in order to pursue their own economic interests of domination and control of the Canadian economy. The process of dependency can also be explained from its internal dynamic which is the creation of what Gary Gereffi calls an "infrastructure of dependency,"⁶⁸ that is made up of a number of state institutions, social classes and processes dedicated to respond to the class interests and economic needs of the U.S. and Canadian elites.

One effect of Canadian dependency vis-a-vis the U.S. is that the state has no alternative but to intervene more vigorously on behalf of its branch plant investors, for example, on behalf of multinational drug companies, in order to secure their investments in an effort to block international competition from other nation-states for their investments. The state, therefore, becomes part of a process of its own demise in power, since it becomes embroiled in defence of foreign branch plant interests rather than protecting its own domestic concerns due to pressures from economic elites from both sides of the border.

The inherent contradictions and consequences in Canadian dependence on

⁶⁸. Gary Gereffi The Pharmaceutical Industry and Dependency in the Third World (Princeton, New Jersey: Princeton University Press, 1983) p-22

American multinationals became visible in the late sixties and early seventies thanks to the increased militancy and social actions of many groups. The pro-nationalist government of Pierre Trudeau attempted to stem the tide of American control of Canadian industry by establishing the Foreign Investment Review Agency in 1974. Its goal was to screen foreign take-overs of Canadian industries and to make sure that Canadians benefit from future investments. But the most significant and controversial action to control foreign dominance of Canadian industry was the introduction of the National Energy Program in 1980. The goal of NEP was to increase the level of Canadian ownership of the oil and gas industry. The reaction to these policies by the American and Canadian dominant classes was to isolate the Liberal government and contributed to the arrival of the Conservative alternative of Brian Mulroney. Finally, our theoretical and public analysis of the state reinforces the notion that its primary function is to guarantee the economic stability and environment suitable for investments.

Our analysis has also suggested the weakness of the pluralist theory which tends to emphasize only the process of decision making but not the consequences and results of those decisions.

Chapter 3

Role of the State, multinational corporations and monopoly patent rights in Canada

General Introduction

On June 23, 1992, the same day the House adjourned for its summer recess, the Federal Conservative government announced in the House of Commons its intention to rewrite Canada's patent laws. Minister for Trade and Industry Michael Wilson introduced the Patent Act Amendment bill (Bill C-91), which would abandon compulsory licenses by extending monopoly patent rights protection from ten to twenty years. It would also be retroactive to December 20, 1991, and prohibit generic companies from exporting their products to other countries.¹ According to the government, there would be only a marginal increase in the price of drugs. Moreover, additional powers would be given to the Patented Medicine Prices Review Board to control the prices of patented medicines. Canadians in the meanwhile would benefit from a healthier brand name industry which would get the incentive it needs to produce a wider variety of available drugs, while at the same time the companies would increase their investments in research and development to the tune of \$500 M over the next five years.

In explaining the reasons for the new patent legislation, Mr. Wilson stated

¹. Canadian Drug Manufacturers Association. "Position Paper." (Toronto: CDMA, September 11, 1992) p-2

that Canada's previous drug policy, which encouraged cheaper prices through the production of generic drugs after the expiry of the ten year monopoly patent protection, "was no longer good for 1992" ² since "Canada was isolated."³ He stated that Bill C - 91 was an inevitable consequence of a new proposal in the draft text of GATT, which Canada was meeting in advance, to give patent holders the full term of intellectual protection that is provided in all sectors of our economy. ⁴ He admitted however that "we were under tremendous pressure"⁵ from the international community to strengthen the intellectual protection for medicines, in order to remain competitive, which is crucial for Canada's future economic prosperity. The government's initiative will however "attract new investments in a high-technology industry and enhance Canada's ability to compete for valuable research work and related jobs." ⁶

The "tremendous pressure"⁷ which multinational pharmaceutical companies have imposed on Canada to rewrite its intellectual property protection laws for pharmaceuticals is a good example of "what an industry that has its act together can

². Toronto Star. "Ottawa's drug bill contradicts free trade." June 25, 1992. p-A11.

³. *ibid.*,

⁴. CDMA, *op. cit* p-2

⁵. Toronto Star, June 25, 1992. *op. cit.* p-A11

⁶. Ministry of Consumer Affairs and Protection. Press Release. June 23, 1992.

⁷. Toronto Star June 25, 1992. *op. cit.* p-A11

do,"⁸ according to a drug company executive, Edgar Davis. The retroactive date of December 20, 1991 of the proposed amendment of the Patent Act coincided with the GATT talks, the same day the Secretary General, Mr. Arthur Dunkel, issued the organization's new proposals on intellectual property rights. The government has conceded that as a result, the prices of drugs will increase under Bill C-91. However, with renewed powers to be given to the Patented Medicine Prices Review Board all excessive price increases will be challenged.

Historic Evolution of Patent Act, 1969 Legislation

Bill C-91 strikes at the core of the previous successful 1969 Liberal government strategy, developed as a consequence of three major government inquiries, which examined allegations that prices for prescription drugs in Canada were among the highest in the world. Evidence of this had been presented to the Restrictive Trade Practices Commission in 1963, the Royal Commission on Health Services, (known as the Hall Commission) in 1964, as well as to the Special Committee of the House of Commons on drug costs and prices, (otherwise known as the Harley committee) in 1967. Each of the three reports identified the extended 20 year patent protection as one of the major reasons why Canadians paid the highest prices for drugs.⁹

⁸. Globe and Mail "Report says drug patent will cost Canadians Billions." November 17, 1992. p-A11

⁹. Gorecki, Paul. Regulating the prices of prescription drugs in Canada: Compulsory Licensing, Product Selection and Government Reimbursement Programs. (Toronto: Economic

It was also revealed that the cost of drugs did not reflect the cost of production. According to an investigation conducted by the Combines Branch, stelazine tablets were imported from a parent company in the United States at a cost of \$1.32 cents per 1,000 tablets.¹⁰ However, the final selling price for this product to Canadian pharmacies after a deduction of sales tax was \$67.70 per 1,000 tablets. Another example involves the drug trancopal which was imported at \$3.88 per 1,000 tablets. After packaging and other costs, the drug was finally sold to Canadian consumers for \$105 per 1,000 tablets.¹¹

According to the director of the Restrictive Trade Practices Commission in his 1963 report, the major reason why Canadians pay one of the highest prices for drugs in the world is because:

the dominance of branches and subsidiaries of United States drug firms and the widespread use in Canada of drug products originated in the United States mean that drug trade in Canada in effect operates under the United States patent system. Products are patented in the United States and their prices set on the basis that the patent holders have a legal monopoly on the sale of these products. Corresponding Canadian patents are then obtained and the drug is supplied to the Canadian market .. at least as high a price as that charged in the United States¹²

Under the Canadian Patent Act, a monopoly is created for a process or

Council of Canada, 1981.) p-1

¹⁰. cited in House of Commons Debates. February 12, 1969, p-6621

¹¹. *ibid.*,

¹². David Fowler and Gordon Myronj The Drug Industry, A case study of the effects of foreign control on the Canadian economy (Ottawa: Canadian Institute of Economic Policy, 1981) p-37

patented product to encourage new inventions, change and innovations in "making the fruits of that invention available in due course to the public." ¹³ It also gives the patentee "the power to prevent others from making, using or selling the patented product or process for a certain period of years." ¹⁴ At the expiry of a patent, multinational drug companies modify their patents by combining the patented drug with other drugs and make "special preparations like liquids, sprays, creams, ointments, capsules and intravenous solutions." ¹⁵ They can also extend the life of a patented drug by "taking out additional process patents at a later date." ¹⁶

In 1923 the Canadian government amended the Patent Act to allow individuals and companies to apply to the Commissioner of Patents for a compulsory license to manufacture a drug under a "process patent." Under Canadian laws only process patents are granted which means that any two companies can produce the same drugs without infringing on "each other's patent as long as they use different processes." ¹⁷ However, the Patent Act amendment of 1923 failed to encourage local competition and the production of patented drugs. Section (41) 3 of

¹³. Hon. John Turner (Minister of Consumer and Corporate Affairs) House of Commons Debates. February 12, 1968, p-6623

¹⁴. *ibid.*,

¹⁵. Joel Lexchin The Real Pushers, A Critical Analysis of the Canadian Drug Industry (Vancouver: New Star Books, 1984) p-163

¹⁶. *ibid.*,

¹⁷. Lexchin, *op.cit.* p-163

the Patent Act explains why:

In the case of any patent for an invention intended for or capable of being used for the preparation or production of food or medicine , the Commissioner shall, unless he sees good reason to the contrary, grant to any person applying for the same, a license limited to the use of the invention for the purpose of the preparation or production of food and medicine but not otherwise; and, in settling the terms of such license and fixing the amount of royalty or other consideration payable, the Commissioner shall have regard to the desirability of making the food or medicine available to the public at the lowest possible price consistent with giving to the inventor the due reward for the research leading to the invention. ¹⁸

Between 1923-1969, only 49 applications were made and 22 licenses were approved. Only one of the licenses granted was to residents of Canada. It has been argued that there were a number of "supply side constraints," ¹⁹ related to the size of the Canadian market which inhibited the manufacture of patented drugs in Canada by generic companies. While the patentee imported a large percentage of the active ingredients in bulk form and prepared the dosage form easily, generic companies were not permitted to import those ingredients as section 41 (3) of the Patent Act demonstrates, and therefore generic companies had to establish their own raw material plants to support their production. Another controversial issue arising out of Section 41 (3) of the Patent Act was its failure to encourage competition. And, according to the commissioner of patents, he was not sure if he had the authority to issue compulsory licenses for the importation of a drug.

¹⁸. cited in Gorecki, op. cit. p.30-31

¹⁹. *ibid.*,

Other constraints included the fact that the period of waiting time for generic companies to get a license approved took from five and a half months to two and a half years. It was alleged that brand name companies wilfully delay the applications for licenses for as long as they could, so as to discourage small manufacturers from "successfully undertaking an application."²⁰ At the same time, costs of advertising for small generic companies were prohibitive. This prevented meaningful competition with the major companies who were already spending 30 percent of their gross earnings on promotion and advertising. As a result smaller companies were restricted to competing by supplying drugs only to hospitals and government agencies. Finally provincial laws with the exception of Alberta did not permit product selection by pharmacists and doctors, while at the same time no data were provided on the therapeutic equivalence of a product.

As a result the compulsory license provision of the 1923 Patent Act failed to encourage generic competition. The Liberal government of 1969 was aware of those disadvantages and was prepared to institute radical changes through an amendment to the 1923 Patent Act in an attempt to encourage generic competition in an attempt to reduce the prices of drugs. However, before the 1969 amendment, the government agreed to remove its seven percent sales tax on pharmaceuticals and to reduce tariffs from 20% to 15% on drugs,²¹ in an effort to reduce the prices of drugs.

²⁰. *ibid.*,

²¹. House of Commons Debates. February 12, 1968. *op.cit.* p-6623

But, after an evaluation was made, it was revealed that while these measures slightly reduced the costs of drugs, "Canadian prices are substantially higher than the lowest prices available elsewhere" ²² and in fact "most drug producers appear to have passed on the bulk of the sales tax removed" ²³ to the consumers. The government therefore decided to push ahead with its amendments.

As part of its package to reduce the prices of drugs, the Liberal government amended Section 41 (3) of the 1923 Patent and Trade Marks Act as follows:

Where, in the case of any patent for an invention intended or capable of being used for medicine or preparation or production of medicine, an application is made by any person for a license to do one or more of the following things as specified in the application, namely:

(A) where the invention is a process, to use the invention for the preparation or production of medicine, import any medicine in the preparation or production of which the invention has been used or sell any medicine in the preparation or production of which the invention has been used, or

(B) where the invention is other than a process, to import, make, use or sell the invention for medicine or for the preparation or production of medicine, the commissioner shall grant to the applicant a license to do the things specified in the application except such, if any, of those things in respect of which he sees good reason not to grant such a license; and, in settling the terms of the license and fixing the amount of royalty or other consideration payable, the commissioner shall have regard to the desirability of making the medicine available to the public at the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention and for such other factors as may be prescribed.²⁴

²². *ibid.*, p-6624

²³. *ibid.*,

²⁴. quoted in Gorecki, *op. cit.* p-36

In other words, the Liberal government's amendment of 1969 to the Patent Act also "provides beyond any doubt that the authority of the commissioner of patents to issue compulsory licenses for patented drugs shall extend to the import of drugs in all forms." ²⁵ It also allowed for the importation and sale of patented drugs by other companies as well as the active ingredients to manufacture. Drugs sold in foreign countries at cheaper prices could now be imported without violation of the Trade Marks Act and sold at cheaper prices compared to those sold in Canada by brand name companies. This means that the patent owner was no longer entitled to an exclusive monopoly protection and could not refuse to grant a license to a prospective individual or company to produce or import a cheaper brand of a patented drug. The monopoly patent protection was also reduced to seven years from a period of twenty.

Accompanying the amendments was the introduction of a series of measures to make generic drugs more competitive in the market. Under the new plan, doctors were informed, through the information services of the Department of National Health and Welfare, of alternative cheaper brands of drugs, their clinical effectiveness, contra-indications and toxicity. The services provided by this agency, it was hoped, would neutralize the dominance of the brand name industry who through their "detail men" were able to control and influence doctors on what drugs

²⁵. Hon. John Turner. (Minister of Consumer and Corporate Affairs) House of Commons Debates. February 13, 1968. p-6624

to prescribe to patients. The intention of the government was to reduce what it claimed was the 30 per cent of the cost of every dollar spent by the drug industry on promotion and advertising.

Reaction of Multinationals.

Intellectual patent protection rights are worth millions of dollars for multinational drug companies. No doubt, the Liberal legislation has been one of the most controversial issues raised in Canadian public policy that has been fought over bitterly between the Conservative party, as defenders of the cause of multinationals, as opposed to the Liberals, at that time, and the NDP, who preferred a solution based on domestic needs. In one of the most complex and difficult episodes in the history of Canadian lobbying, multinationals launched a vigorous campaign to prevent the amendments. Threats and warnings were made to the public on the future of the brand name industry in Canada. They complained that they would eventually have to close their Canadian operations and the lives of millions of Canadians would be at a risk as a result.

Quebec's Defence of the Industry in the 1960's.

Some members of the Federal opposition Conservative party from Quebec opposed the 1969 legislation on the grounds that it would affect new investments in the province. Quebec's Liberal M.P. Raymond Rock described the proposed legislation as a threat to the 21 Montreal- based pharmaceutical companies and thousands of their employees, many of whom, according to him, were graduates of

Universities in Montreal and McGill. Rock also introduced, for the first time in the debate, a token of regionalism, in his defence of the industry. He questioned the support for the legislation by the Liberal representative of St. John's West, Newfoundland, Mr. Cashin, asking what would be his reaction if the Federal government decided to import cheaper fish from Russia or Portugal? According to Rock, he had no doubt that Cashin "would play a different tune on his fiddle if he had a few pharmaceutical companies in St. John's Newfoundland."²⁶ However, despite the apprehension of Rock, investments in Quebec did not decrease, but rather increased as a result of the legislation as will be demonstrated later.

Response of Multinationals

Despite the opposition from the multinational industry and to a lesser extent from some Quebec MP's and the opposition Progressive Conservative party, the government proceeded with its amendments. It came as a disappointment to the industry and brought to a temporary end "one of the strongest and most boorish lobbies "ever mounted on Parliament Hill," ²⁷ According to John Gilbert, an NDP Member of Parliament, during the debates on the amendment of the Patent Act of 1923, "The drug representatives were lined up in the galleries and there was a constant running back and forth with speeches they had prepared for certain

²⁶. Hon. Raymond Rock. (Jacques-Cartier-Lasalle) House of Commons Debates. op. cit. p-6698

²⁷. John Sawatsky and Harvey Cashmore "Inside Dope." This Magazine August/September 1986, p-6

members of the opposition."²⁸ The Progressive Conservative party, which opposed the amendments vehemently, eventually acknowledged defeat. According to J.M.Forrestall (Halifax) a member of the Conservative party "as far as his party and the PMAC were concerned it (the amendment) was inevitable and there was no use in fighting further."²⁹

Members of the Pharmaceutical Manufacturers Association of Canada (PMAC), although conceding defeat were anxious to thwart the effects of compulsory licenses. As much as \$250.000 was spent annually in a campaign to prevent generic companies from taking advantage of compulsory licenses.³⁰ The bill was immediately challenged through a legal action from American Home Products (a member of the PMAC) which managed to delay the implementation of the bill by a year. Of 69 licenses issued under new compulsory license laws there were, by the end of 1971, 43 lawsuits filed against generic manufacturers.³¹ The purpose of these lawsuits was mainly to delay the production of generic drugs while at the same time to "to inflict legal costs on their opponents."³² According to an official "they were

²⁸. Ronald Lang The Politics of Drugs. The British and Canadian Pharmaceutical Industries and Governments: a comparative Study (U.S.A, England: Saxon House/ Lexington Books, 1974) p-247

²⁹. *ibid.*,

³⁰. Lexchin. Pharmaceutical and Patents. p-2

³¹. Joel Lexchin "Pharmaceutical , Patents and Politics: Canada and Bill C-22." International Journal of Health Services. Vol.23, Number 1, 1993, p-148

³². Sawatsky and Cashmore. *op. cit.* p-7

using the same arguments all the time,"³³ up until the end of 1986.

Effects on Prices

The introduction of the 1969 amendment to the Patent Act brought the prices of drugs to Canadian consumers to a dramatic low. According to Sawatsky and Cashore,

The same quantity of Valium that sells for \$345.93 in the U.S goes for \$80 in Canada. The reason Hoffmann-LaRoche, the patent holder, discounts the Canadian prices by more than seventy five percent is that the generic equivalent, Diazepam, sells as low as \$2.31. Pfizer charges \$431.58 for Chlorpropamide in the U.S and only \$141.80 in Canada because it has to compete with a generic called Diabinese at \$19.03.³⁴

Hoffmann-LaRoche could not bear the new competitive spirit of the market and began "undercutting its generic competition."³⁵ Within a period of a year, it distributed free of cost a total of eighty-two million pills of Valium at a value of \$2.6 M.³⁶ Under the Combines Investigation Act, charges were laid against the company which was found guilty of selling a product at an "an unreasonably low price [for the purpose] of lessening or eliminating competition."³⁷

³³. *ibid.*,

³⁴ *ibid.*, p-8

³⁵. *ibid.*,

³⁶. Lexchin. The Real Pushers p-20

³⁷. *ibid.*,

Effects on Generic Companies

At the beginning, the opening up of Canada's pharmaceutical market through competition made it less expensive for generic companies to import patented drugs rather than to manufacture here in Canada, since generic companies had to "prove the bioequivalency, and in some case had to repeat the tests that brand name companies had already conducted."³⁸ This was a time-consuming and costly venture; as a result, generic manufactured drugs often took a number of years before they reached consumers, which meant a delayed competition against monopoly patent holders. Finally, upon the introduction of generic drugs, the cost was on an average 40 percent cheaper than brand name drugs.

Effects on the Multinational Drug Industry

Despite the introduction of compulsory licenses provincial health care and drug benefit program assistance bills kept increasing. Although generic drugs reduced the profit level of multinational drug companies by some \$85 to \$165 M, by the end of 1980 the "average before tax profit on capital employed for the pharmaceutical industry was 22.8 percent or 73 percent higher than that for all manufacturing industries."³⁹ By 1983, according to the 1985 Report of the Commission of Inquiry on the Pharmaceutical Industry, savings to consumers based on the calculations of 32 out of 42 compulsory licenses in 1983 were in the vicinity

³⁸. *ibid.*,

³⁹. Lexchin. The Real Pushers op. cit. p-173

of \$211 million annually,⁴⁰ which accounted for only 3.1 percent of the brand name pharmaceutical market.⁴¹

Also, the industrial output of the multinational drug industry increased in constant dollars between 1967 and 1982 by 133 percent compared with an increase for all manufacturing of only 44.5 percent.⁴² It is presumed that this increase can be attributed to the development of the publicly-financed drug programs and the 'greying' of the population. The assets of the industry grew from \$256 M in 1967 to \$1.3 billion in 1982. This represents an increase of 410 percent compared to 351 percent for all of the nation's manufacturing.⁴³

Employment within the industry increased by 29 percent between the years 1967 and 1982 compared to less than four percent for the Canadian manufacturing sector during the same period.⁴⁴ Research and development during the same period increased by 448 percent, even though it still remained the lowest for the developed world. Profit levels continue to increase at an incredible rate and by the end of 1987 the rate of return on equity of the industry surpassed all other industries in Canada by a tremendous margin.⁴⁵ The levels of profits exceeded that of most developed

⁴⁰. Roy Davidson "The scope of Patents." Policy Options December 1986, p-4

⁴¹. Lexchin. "Pharmaceutical, Patents and Politics." p-149

⁴². Davidson. op. cit. p-3

⁴³. *ibid.*,

⁴⁴. Davidson. op.cit. p-3

⁴⁵. Lexchin, "Pharmaceuticals, Patents and Politics." op. cit. p-149

countries with the exception of the U.S.⁴⁶ (see next page).

⁴⁶. Harry Eastman Report of the Commission of Inquiry of the Pharmaceutical Industry (Ottawa: Canadian Government Publishing Centre, 1985) p-277

Rate of return on equity for pharmaceutical industry, before taxes, 1972 - 1987
(Rate of return, %)

	Pharmaceutical Industry	All Industry	Ranking of Pharmaceutical Industry
1972	24.7	14.1	8
1973	24.3	19.7	17
1974	27.4	22.8	19
1975	25.0	17.8	12
1976	22.7	15.8	15
1977	21.4	14.7	16
1978	22.7	17.4	20
1979	28.3	21.9	17
1980	30.1	20.1	10
1981	31.0	17.4	6
1982	30.0	5.4	7
1983	33.9	9.9	3
1984	40.3	15.7	2
1985	41.1	12.7	3
1986	45.5	14.9	1
1987	42.2	16.2	1

Source: Statistics Canada. *Corporation Financial Statistics - Detailed Income and Retained Earning Statistics for 182 Industries*.

The evidence provided above demonstrates that the multinational pharmaceutical industry successfully adjusted to the 1969 legislation and, despite its threats to close its operations in Canada, they chose to remain here.

Despite the overwhelming financial success of the industry, the PMAC

continued its lobbying efforts in an attempt to get government to change Section 41(4) of the Patent Act in exchange for voluntary price cuts and an increase in investments, manufacturing and research in Canada. However, according to Dr. Joel Lexchin, an examination of the PMAC promise revealed that "most of the new research and development and manufacturing promised by the industry was either already planned or was to be financed through government incentive programs."⁴⁷ The industry once again threatened to pull out of Canada if extended intellectual property rights were not given and warned of future plant closings and a reduction of research and development.

Impact of the Change on Quebec

The multinational industry's attempt to change the 1969 legislation received key support from some of the Liberal and Conservative members of the Federal parliament from Quebec and other provinces on various occasions. For example, the leading spokespersons from Quebec were Hal Herbert (Liberal-Vaudreuil, home base of Hoffmann-La Roche), David Berger (Liberal-Laurier) and Andre Ouellet (Liberal-Papineau-Saint-Michel). Also there were Dr. Stanley Hudecki (Liberal-Hamilton West) Gordon Gilchrist (PC-Scarborough West) and Dr. Gary Gurbin (PC-Bruce-Grey). Their efforts continued despite the fact that the industry in Quebec had grown at an average rate of 9% from 1969 to 1974. In 1974, it was

⁴⁷. Lexchin. The Real Pushers. p-176

ranked as the province's 21st largest industry. Its contribution to the Quebec G.N.P in 1975 was \$350 million and Quebec accounted for 60% of drugs produced in Canada. Total output produced by the industry in 1975 was \$290 million while investments in land and buildings were to the tune of \$130 million.⁴⁸ By the mid-seventies the area of concentration for the multinational drug industry was in Montreal and Toronto areas with a ratio of 60 to 40 in favor of Montreal.

However, by the end of 1970's, there was a massive exodus of many pharmaceutical companies from Montreal to Toronto. But, before this change was occurring, the PMAC in 1977 was already reminding the Quebec government of the positive economic and social support the industry was providing to the province. According to the industry, it was up to the Quebec government to continue "to maintain a climate enabling the industry to develop and to continue its contribution to the economy."⁴⁹ It is not clear what message the industry was sending to the Quebec government. However, the decision by many multinationals to relocate their facilities to Toronto was probably a conscious effort, to get the Quebec government involved in defence of the multinational industry, in its effort to change the 1969 legislation, since Quebec was now losing out on new investments by the industry.

⁴⁸. Pharmaceutical Manufacturers Association of Canada. The Pharmaceutical Industry in Quebec. (Ottawa: PMAC, 1977) p-3

⁴⁹. *ibid.*,

R.C Kenneth, gives some of the reasons for the relocation of the industry to Toronto;

1. General gravitational shift of market westward applying to all commodities.
2. Toronto is the focal point of the medical-scientific community. University, hospital and research facilities are readily available.
3. Toronto provides the advertising and marketing environment required for production promotion.
4. Qualified technicians and production staff are available.
5. Toronto is centrally located to better serve the national market with excellent transportation facilities.
6. Toronto provides a politically stable, provincially receptive trade climate, with few language constraints.⁵⁰

While R.C Kenneth provided some reasons for the relocation of drug industries to Toronto, it was also suggested by some analysts that, as a result of increased sales and expansion of the industry, it was no longer economically feasible to continue operations at the Montreal facilities since it would require costly renovation and modernization of the "old" Montreal plants. Therefore, the alternative was to build new facilities, rather than renovating the old ones. As a result, Toronto was chosen. The new investments, according to an industry official, "resulted in a very modern, highly productive industry, with the potential to increase capacity and remain competitive."⁵¹

In 1982 and 1983 Hoffman-LaRoche and Ayerst closed some of their

⁵⁰. R.C. Kenneth The Pharmaceutical Industry in Canada. (Ottawa: Supply and Services Canada, 1982) p-13

⁵¹. *ibid.*,

manufacturing and research facilities in Montreal, Quebec. Members of the PMAC attributed the closure to a lack of confidence in Canada's intellectual property protection laws. But according to John Sawatsky and Harvey Cashore, these facilities were closed mainly for economic reasons as part "of a world-wide trend toward centralized research in the United States, Switzerland and West Germany."⁵² The chairman of Ayerst, Donald Davies, explained "It's simply far more efficient to do all our research in one place."⁵³ The loss of 350 jobs from these industries, and the high unemployment rate in Quebec, encouraged the lobbying efforts by the PMAC, who concentrated most of their attention on the Quebec Liberal caucus in Ottawa, since quite a large majority of the pharmaceutical industry was based in Montreal. The PMAC promised to invest more in Quebec in exchange for a change in the intellectual patent laws.

Liberal Government Attempts to change 1969 Legislation

The Deputy head of the Liberal caucus, Andre Ouellet, was also the Minister of Consumer and Corporate Affairs. His responsibility for the protection of Consumers Affairs and, as the chief whip, in defence of the political interests of his Quebec caucus made him an 'ideal' source of influence for the PMAC. John Sawatsky and Harvey Cashore in their article "Inside Dope," described the position

⁵². Sawatsky and Cashmore. op. cit. p-7

⁵³. quoted in Lexchin. The Real Pushers op.cit. p-177

of Mr. Ouellet as "The proverbial fox,"⁵⁴ charged with the responsibility of "guarding the hen house."⁵⁵

During his term in office as Minister of Consumer and Corporate Affairs, (1982-1983) Ouellet responding to pressure in the House of Commons wasted no time in appointing a committee, to review the issue of compulsory licenses.⁵⁶ The head of the committee was Martin O'Connell, a consultant and lobbyist for Eli Lilly and the PMAC and a former Liberal MP. O'Connell recommended an extension of market exclusivity for patented drugs for a period of eight years.⁵⁷ This was followed by a proposal by Mr. Ouellet, to amend Canada's Patent Act "to create a better climate for investment and research in Canada,"⁵⁸ and the recommendation of a study of the following possibilities: "market exclusivity, a variable royalty rate and allowing compulsory license on only some drugs,"⁵⁹ as a guide for consideration. The announcement by the Minister brought about protests from the National Anti-Poverty Organization, the Consumers Association of Canada, the Medical Reform Group of Ontario and many other social groups.

It is not clear whether the protests by various groups contributed to Mr.

⁵⁴. Sawatsky and Cashmore. op. cit. p-9

⁵⁵. *ibid.*,

⁵⁶. House of Commons Debates. April, 1983

⁵⁷. House of Commons Debates. April 11, 1983. p-24341

⁵⁸. Lexchin. The Real Pushers. op.cit. p-179

⁵⁹. Sawatsky and Cashmore. op.cit. p-9

Ouellet's demotion on August 1983 in a cabinet shuffle to the Ministry of Labor. The new Minister of Consumer and Corporate Affairs was Judy Erola, the present head of the PMAC. According to her, the lobbying was so intense by the Quebec caucus, the PMAC and groups opposed to any increase in the prices of brand name drugs that it was perhaps "the strongest I've ever seen." Erola was accused of "retarding the development of drugs to cure cancer and heal all sort of illness," by the multinational drug industry, and being personally responsible for "people's death,"⁶⁰ by not doing anything to help the industry to repeal the 1969 legislation.

The events that unfolded were too 'hot' for the government to handle especially in an election year. The Liberal government did not want to isolate its Quebec constituency. Therefore, in an attempt to avoid further conflict, Erola appointed a one-person commission of inquiry, to be headed by the eminent University of Toronto economist, Professor Harry Eastman.

Election of Conservative Government and Bill C-22

By the time the Eastman Report was finished, a new government led by the Progressive Conservative party took power with a strong Quebec majority. Before winning the 1984 Federal Elections, Brian Mulroney had already pledged his support to the multinational drug industry while on an election campaign visit to Montreal.⁶¹ Mulroney was also fully informed by President Reagan while on a visit

⁶⁰. *ibid.*, p-10

⁶¹. Lexchin. "Pharmaceuticals, Patents and Politics." p-153

to Washington, shortly before he won the election, on how the U.S felt about the issue of 'intellectual property', and the 1969 legislation.⁶²

The Eastman Report was presented to the new Progressive Conservative government in 1985. It concluded that compulsory licenses were working well, and had saved Canadians millions of dollars and should be kept. There was no evidence that the profitability of pharmaceutical companies was in any way hampered because of compulsory licenses. The report however recommended that generic companies pay a much higher royalty rate to brand name companies than the present four percent rate. With the new Conservative government in power, multinational drug companies demanded an immediate freeze on the granting of compulsory licenses on all drugs, and campaigned once again for new legislation to extend monopoly patent protection. The strength of the PMAC lobby forced the new Minister of Consumer and Corporate Affairs, Michel Cote, to make an agreement with representatives of the Liberal party and members of the Canadian Drug Manufacturers Association (representatives of generic manufacturers) to agree to a temporary moratorium that would prevent the issuing of further compulsory licenses for a period of 120 days. In exchange, PMAC companies promised to stop suing generic companies over old patents.⁶³ But within a couple of days of the signing of the moratorium, a member of the PMAC broke its side of the deal by instituting

⁶². *ibid.*, p-154

⁶³. *ibid.*, p-154

legal action once again against a member of CDMA over the issue of Patents. The violation of terms of the moratorium led other generic companies to apply for more compulsory licenses.

Perhaps the most significant change in favor of members of the PMAC was a commitment by the Conservative government in 1985 to a free-trade deal with the U.S, which exposed it to stronger lobbying from the U.S government, the PMAC and the Quebec caucus of the Conservative party for an amendment of the Patent Act.⁶⁴ At the first official meeting of Brian Mulroney as Prime Minister of Canada with President Ronald Reagan in Quebec City on March 1985, the concerns of the multinational drug industry were raised by the Americans.⁶⁵ Following the meeting, Vice-President George Bush announced that Canada had made a commitment to change its Patent Act.⁶⁶ By the end of June 1986 he "publicly complained about the delay in the changes."⁶⁷

Quebec's support for stronger intellectual protection laws was strengthened, however, when it was revealed that Quebec's share of employment out of 134 establishments within the pharmaceutical industry had been reduced from 47.1% in 1976 to 39.3% in 1985. Ontario gained from Quebec's loss, from 50.5% in 1976 to

⁶⁴. Swatsky and Cashmore. op. cit. p-9

⁶⁵. Linda McQuaig The Quick and the Dead (Toronto: Penguin Books of Canada, 1991)

⁶⁶. Swatsky and Cashmore. op. cit. p-10

⁶⁷. Lexchin. "Pharmaceuticals, Patents and Politics." op.cit. p-151

57.4% in 1985. Also, Quebec's share in shipments and added value dropped from 46.5% and 45% in 1976 to 40.8% and 41.85 in 1985, while Ontario's share grew from 51.2% and 53.6% to 56.9% and 57.0% by 1985.⁶⁸ It should be noted, however, that the accuracy of these figures is questionable since they failed to take into account the impact of increased generic production in Ontario and the introduction of advanced technology by multinationals.

The Prime Minister, in response to pressure from the multinational industry and the Quebec and American governments, declared that Canadians were "acting as a scavenger in the area of intellectual property."⁶⁹ But, the Canadian government was reluctant to acknowledge that its decision to extend intellectual patent property protection was something it had agreed to as a condition for free trade. However, an examination of the final text of the agreement confirmed suspicions of a linkage between compulsory licenses and a free trade deal. According to the proposed agreement, the intent was "to make progress towards establishing of adequate and effective protection of pharmaceuticals in Canada by liberalizing the compulsory license provision."⁷⁰ Some members of the Progressive Conservative party were

⁶⁸. The Quebec Economy 1987. (Minister of Supply and Services, Canada. June, 1988) p-93-94

⁶⁹. Swatsky and Cashmore. op.cit. p-12

⁷⁰. Lexchin. "Pharmaceutical, Patents and Politics." op.cit. p-151

appalled and "demanded the removal of that section"⁷¹ from the final text of the agreement. Nonetheless, in return for free trade with the U.S, the Mulroney government passed legislation under Bill C-22 to extend monopoly patent protection from seven to ten years.

Introduction of Bill C-22

The introduction of Bill C-22 in 1986 was more about pleasing the U.S. government and the Quebec caucus of the Conservative party than it was to increase research and development in Canada. Prime Minister Brian Mulroney and his Quebec caucus developed a grand "vision of a high-tech pharmaceutical industry that would benefit Quebec particularly and that led them to push for a weakening of the compulsory license provision"⁷² in Canada. The PMAC in turn has nurtured that vision by making a number of promises to increase their members level of investments in research and development in exchange for a change in the Patent Act.

The Mulroney-led Conservatives introduced Bill C-22 in April 1986 with a promise "to review more extensive patent protection "⁷³ within a few years. In the fall of 1986 Harvie Andre, Minister of Consumer and Corporate Affairs, introduced Bill C-22 that extended monopoly patent protection to a period of ten years.

⁷¹. Washington Post U.S bowed to Canadian demands to change pact. October 17, 1987. p-A13

⁷². Davidson. op.cit. p-5

⁷³. Ruth Scher "Patent Greed." The Facts Vol. 13, No.3, December 1992. p-38

According to the government, Bill C-22 would create

an unprecedented private sector investment in research and development during the next ten years of \$1.4 billion over and above the present trend in the industry, thereby directly creating some 3000 scientific and research related jobs.⁷⁴

Estimates also put forward by the federal government suggested that 1500 new research and development jobs would be created by 1991 and by 1996 there would be another 1500 jobs. According to the Conservatives, changes had to be made under Bill C-22 in order to harmonize Canada's policy on intellectual property with those of other developed countries, to enhance Canadian chances of becoming at "the forefront of leading nations in pharmaceutical research and development."⁷⁵

However, according to the information provided below, to make Canada the 'forefront of leading nations' of research and development, the PMAC member companies would need to triple their promised expenditures in research and development before the end of 1996, since Canada ranked second to last of all developed countries.

⁷⁴. Canadian Drug Manufacturers Association. The Straight Facts No.5, September. 1991,

⁷⁵. *ibid.*,

R & D Expenditures by the Pharmaceuticals Industry As a Percentage of Industry Sales (Selected Countries, 1989)

Country	R & D/Sales Ratio
Sweden	21.8
United Kingdom	20.9
West Germany	17.9
United States	14.2
France	14.1
Japan	13.9
Denmark	10.7
Norway	10.6
Finland	9.8
Italy	9.6
Belgium	9.0
Netherlands	8.8
*Canada	8.2
Spain	2.6

(Source: SCRIIP"Yearbook 1991", Patented Medicine Prices Review Board, Second Annual Report 1990)

In spite of the weakness of the PMAC promises, the government argued that measures undertaken under Bill C-22 were justified because of

a commitment on the part of the innovative pharmaceutical industry to advance Canada into the forefront of leading nations in pharmaceutical research and development by doubling the ratio of R&D to sales under 5% today to 10% by 1995.⁷⁶

The PMAC immediately welcomed the government's initiative as something which it had been fighting for a long time and pledged

we will guarantee you that we will keep the price of drugs below the cost of inflation...[and] we will increase our level of R & D to eight

⁷⁶. *ibid.*, p-3

percent in 1991 and ten percent by 1995.⁷⁷

Impact on Jobs

The proposal by government to increase monopoly patent protection for brand name companies was received with tremendous opposition from various groups including provincial governments, organizations involved with health care, senior citizens and anti-poverty organizations. Fears were expressed by many that this was only the first phase of a grand attempt to "Americanize" the Canadian pharmaceutical industry. The government, as a result, was forced to go on the defensive, to convince the public that 3,000 more professional scientific jobs would be created, despite the fact that its own department of Consumer and Corporate Affairs advised it in a report in spring 1985 that only 1,700 jobs would be created in the professional category, while another 650 jobs would be created for laboratory technicians and the remaining 650 jobs would be in the field of managers, clerks, cleaners etc.⁷⁸

Notwithstanding, the projections and promises for new scientific jobs, multinational drug companies failed to keep their promise. According to the Montreal Gazette, "only 1,386 jobs were created between 1987 and 1990, and nearly half of these jobs were in marketing and sales with only a third in research

⁷⁷. Hon. Ron MacDonald (Dartmouth) in House of Commons Debates. September 17, 1992. p-13266

⁷⁸. quoted in Lexchin, Pharmaceuticals, Patents and Politics. op. cit. p-153

and development."⁷⁹ But, while some jobs were created by the end of 1990, "public evidence indicates that the multinationals are actually eliminating jobs in Canada."⁸⁰ At the same time 700 jobs were lost due to plant closures in the process.⁸¹

Impact on Research and Development

It is debatable how much the multinational drug industry has complied with its promises to increase investments in R & D. Allegedly these companies had been preparing since 1985 for changes in the Patent Act. As a result they

managed to diminish the proportion of their sales invested in research and development to the lowest level in the decade in order to afterwards say that they had increased their investments in research and development.⁸²

As was the case of Quebec, this deception by the industry proved to be a successful ploy to win further changes to the patent act in 1992, under Bill C-91. The Patent Medicine Price Review Board in its fourth report in 1992 pointed out that the brand name pharmaceutical industry had reached 9.6 percent of its promised target for R & D for 1991 out of total sales of \$4 billion.⁸³ The generic industry on the other

⁷⁹. Montreal Gazette "High quality jobs for drug industry include cleaners." December 17, 1986 p-B1

⁸⁰. *ibid.*,

⁸¹. *ibid.*,

⁸². Hon. Howard McCurdy (NDP-Windsor-St. Clair,) House of Commons Debates. November 17, 1992. p-13503

⁸³. Patents Medicine Prices Review Board. Fourth annual report for the year ended December 31, 1991. p-2

hand, had invested over 10 percent of the industry's sales of \$400 M in 1990.⁸⁴ At the same time, it would seem that the multinationals almost reached their target in R & D, although most of it was paid by Canadian taxpayers. In Quebec, for example, for every dollar the industry boasted of putting into R and D, seventy cents of that amount was contributed by the Quebec and Federal governments.⁸⁵

Nevertheless, it is estimated that approximately 26.5 percent of total expenditure on R & D was spent on basic research which involves the creation of new drugs.⁸⁶ The rest was spent on clinical research which involves the testing of new drugs discovered in other countries on animals and volunteers, in order to pass Canadian food and drug regulations. A large proportion of other research funds was also spent on "product development," to find out which products and drugs, such as pills, tablets, solutions and creams, consumers prefer most.

Impact on Prices

The effectiveness of the Patent Medicine Price Review Board which was created under Bill C-22 to monitor the prices of drugs is seriously in doubt. Its renewed authority to roll back excessive price increases under Bill C-91 "will by no means serve as a substitute for price competition to lower the prices of drugs,"⁸⁷

⁸⁴. Canadian Drug Manufacturers Association. The Straight Facts No.6, December 1, 1991

⁸⁵. House of Common Debates. September 17, 1992. p-13266

⁸⁶.ibid.,

⁸⁷. Canadian Drug Manufacturers Association. Position Paper (CDMA, 1992) p-3

which the government estimated would rise at about \$129 M annually.⁸⁸ It has been alleged that the board is not fully equipped to control the cost of new drugs which patentees are known to introduce at excessively high prices. Multinational corporations are known to have ignored the PMPRB's price guidelines without any action being taken against them, "a situation which accounts for non-compliance rates at 30-40 per cent since 1987."⁸⁹

Often described as a "toothless tiger," the Board failed to roll back increases in the prices of drugs, despite the commitment given by the industry in 1987 to maintain its prices below the level of inflation and, to enforce government's regulations.⁹⁰ The inability of the board to perform its duties was confirmed by its own chairman, in its fourth report to Parliament. According to him,

The high number of prices out of compliance (that is breaking the rules) suggests either that some patentees follow a strategy of setting high introductory prices so as to benefit from the temporary gain, or to resist the Board's guidelines.⁹¹

As many as 40 percent of new drugs introduced in the market were sold at prices beyond the guidelines of the PMRB.⁹² The prices of drugs, after Bill C-22,

⁸⁸. Globe and Mail "Drug firms promise to invest \$400-million." June 24, 1992. p-A1

⁸⁹. Canadian Drug Manufacturers Association. Position Paper op.cit.

⁹⁰. House of Commons Debates. November 17, 1992. p-13506

⁹¹. Patented Medicine Prices Review Board. op. cit. p-5

⁹². Hon. Ron MacDonald.(Liberal- Dartmouth) House of Commons Debates. September 17, 1992. p-13272

exceeded the increase "in the CPI by less than 2 percentage points, 6.2 percent points as compared to 4.4 percent for the CPI."⁹³ The Board, despite acknowledging that it was not capable of effectively monitoring the prices of drugs, has claimed that there has been only a moderate increase of 3.2 percent.⁹⁴

Evidence from the Ontario Drug Benefit Plan reveals that consumers paid 13.2 percent more for drugs and not 3.4 percent as claimed by the PMRB, during the period of implementation of Bill C-22 to 1991.⁹⁵ The Manitoba Health Insurance Plan recorded an annual increase in prices of 12.3 percent.⁹⁶ Green Shield, one of the nation's largest operators of drug benefit plans, in a study conducted on the prices of drugs, "confirmed the worst suspicions linking extended patent protection to higher prices."⁹⁷ It concluded that between the years 1987-1991 the average cost of a prescription claim rose 11.4 percent annually which is two and a half times the rate of inflation.⁹⁸ According to the study, the average cost per drug (per claim for insurance) "rose 53.8 percent over a four year period while the Consumer Price

⁹³. *ibid.*,

⁹⁴. Patented Medicine Prices Review Board. *op.cit.*p-5

⁹⁵. cited in House of Commons Debates. September 17, 1992, p-13267

⁹⁶. *ibid.*,

⁹⁷. Scher. *op. cit.* p-39

⁹⁸. Green Shield Prepaid Services Inc. A Report on Drug Costs (Willowdale, Ontario: Green Shield, April 1992)

Index rose by only 20.9 percent."⁹⁹ The prices of new drugs have had a tremendous impact on average drug costs because most new drugs are much more costly. "The average cost per claim for new drugs in 1991 was \$34.12, more than twice the \$16.04 average claim cost for existing drugs."¹⁰⁰

The above increases in the prices of drugs came as no surprise. According to Joel Lexchin, even the government at the time of the introduction of Bill C-22 had confirmed a report, by its own Department of Consumer and Corporate Affairs, that it expected a \$100 M increase in the prices of brand name drugs between 1987 and 1991, and as a result offered the equivalent sum to provincial governments, to help cushion the blow on provincial budgets.¹⁰¹ The above evidence proved that there was a much more substantial increase in prices.

Despite the industry's failure to keep its promises under Bill C-22, the government reiterated that Bill C-91 was necessary in order to harmonize Canada's monopoly patent protection laws with the United States and the European community. Canadians would therefore stand to lose on new investments by the multinational drug companies "that had kept their 1987 commitment in terms of research and development and would leave Canada,"¹⁰² if the industry did not get

⁹⁹. *ibid.*,

¹⁰⁰. Scher. *op. cit.* p-39

¹⁰¹. Lexchin. "Pharmaceuticals, Patents and Politics." p-154

¹⁰². Ministry of Consumer Affairs. *op. cit.* (Press Release.) p-2

the protection it needs. According to the government, the urgency to act quickly was inevitable if Canada was to remain competitive.

Role of the Bureaucracy

An analysis of the role of the bureaucracy in the policy making process would not be complete without reminding ourselves of the past political role of the Progressive Conservative party in pushing for greater intellectual property protection since the introduction of compulsory licenses in 1969 to the assumption of power in 1984. Also significant are the key support given from its Quebec wing and to some extent the silence of the Liberal party during the debates on Bill C-91. Consideration must also be given to the international power and influence of the industry and the role of the American government in GATT negotiations and Canada's willingness to participate in FTA and NAFTA which confirms that regardless of the position of the bureaucracy extended intellectual property protection rights would be inevitable.

Given the fact that there was a clear political statement by the Mulroney government in support of multinational drug corporations on intellectual property rights, the expectation is that the bureaucracy will act accordingly to boost the government's position. From a constitutional point of view it is the minister who is responsible for the formulation of policy based on his or her position as the elected representative. The role of the civil servant, it is argued, is to appropriately follow the orders of his or her superior. The debate as to the theory and practice of the

distribution of power and influence of the bureaucracy and the elected representative has been dealt with sufficiently elsewhere. However, at issue for our analysis is to appreciate and understand the role and function of the bureaucracy on Bill C-91.

In order to assess the bureaucracy, it is necessary to analyze its role vis-a-vis the actions of elected representatives and the representatives of the local generic industries on Bill C-91. In their announcement that Canada would eliminate compulsory licensing on January 14, 1992, Michael Wilson, Minister of Industry, Science and Technology Canada, and Pierre Blais Minister of Consumer and Corporate Affairs confirmed that

We have had ongoing and intensive discussions with both the generic companies and the brand name companies in the last month and, in particular, since the tabling of the GATT proposals on December 20, 1991.¹⁰³

The above statement claims that there had been consultation between December 20, 1991 and January 15, 1992 with the generic sector before the decision was made. Bernard Sherman, president of Apotex Inc, in response to the minister's statement claimed that there were no consultations with the generic sector. According to him, on January 10, 1992 the Assistant Deputy Minister of ISTc, J.C.MacKay, faxed him and Leslie Dan, President of Novapharm, a letter which stated that

¹⁰³. Bernard Sherman. "In the matter of Bill C-91 before the Parliament of Canada." Mimeo, 1992. Note, all the data and information used on this topic are taken from the same author.

As you are aware, GATT negotiations are proceeding and member countries are considering the Dunkel proposal which includes a section on intellectual property protection measures.

Within this context, I would like to invite you to meet with us to find out how you think the Dunkel proposal will impact on your company.

It is important to remember that shortly after the Dunkel proposal was made Canada was the only country to immediately approve it. The Director General for the Chemicals and Bio-Industries Branch of the ISTC, Dr. Elizabeth Dickson, requested from Mr. Sherman and Mr. Dan their urgent input of the impact on the generic sector before January 13, 1994. Dr. Dickson was told that it was impossible to do so in a few days and they would need at least a week to do so. Despite that, the government's announcement was made on January 14, 1992.

According to Mr. Sherman,

In view of the fact that the announcement was made on January 14, 1992, I believe that Dr. Dickson must have known on January 10, 1992, contrary to the content of Mr. Mackay's letter, that the decision would be announced on January 14, 1992. I thus believe that the only possible explanation for her insistence that our analysis be submitted by January 13, 1992 was to put ISTC in a position where it could claim that we had been consulted before the announcement was made. ... , it became clear that the government had been involved in extensive discussions with the foreign-owned multi-national brand name companies, just as was acknowledged in the release on January 15, 1992, notwithstanding that the government failed to seek or obtain meaningful input from the Canadian-owned generic sector as to the adverse impact on these sectors and on the health care system.

The evidence provided so far demonstrates some confusion and deliberate misrepresentation of the facts between members of the bureaucracy and elected representatives. To compound matters further, the presentation of the estimated cost impact of increased intellectual property protection by the ISTC by members of the

bureaucracy was blatantly biased. According to a release by officials of the ISTC and the Ministry of Consumer and Corporate Affairs

The cumulative increased cost of drug purchases by physicians and hospitals over the period 1992 to 1996 due the elimination of compulsory licensing is estimated at \$129 million (constant dollars), less than \$1 per Canadian per year, or less than 1/20 of one percent of the total health care bill in Canada.

The increases in costs of purchases by pharmacies and hospitals of all prescription and behind-the-counter drugs, due to the removal of compulsory licenses, is predicted to be 0 percent in the first year, gradually increasing to less than 2 percent annually by the year 2000.

The sources of input to the above analysis on the proposed increases in the prices of drugs according to J.C. Mackay, ADM of the ISTC came from the following sources,

- (a) representations from the foreign-owned multi-national brand name companies as to investment;
- (b) The "trade community" in GATT and NAFTA negotiations; and
- (c) "out of the civil service."

Again, as can be noted, no input from the generic sector was included. The government's report (quoted above) on the purported increases in the prices of drugs have been proven to be not accurate. According to the Patent Medicines Prices Review Board, within two months of the passing of Bill-91, Canadians were paying one of the highest prices for drugs once again in the world as will be demonstrated later.

The nature and scope of the role of the bureaucracy on Bill C-91

demonstrates the true representativeness and responsiveness of its functions to the public. An understanding of its role must be linked to a wider theory of society that explains our perception and understanding of the role of the state within a liberal market oriented system, the dominant characteristic of which is its subordination to the interests of capital. The state's role is linked to the importance of production to satisfy the material needs of society. However, it is the way in which production is organized and the social relations that are developed that provide the basis of understanding the role of the state and the bureaucracy.¹⁰⁴ Throughout the history of Canada, the state has provided the means necessary, through grants, subsidies and investments on infrastructure works, to enhance the accumulation of capital. It is the dominant class that benefits from state intervention and protection through its coercive apparatus and accumulative role which places its influence above others in the determination of the policy process

Bill C-91, Social and Economic Consequences.

According to the Minister for Trade and Industry Michael Wilson, it was inevitable to amend the monopoly patent act under Bill C-91 (see page 87). Yet, he also complained of the “tremendous pressure”¹⁰⁵ imposed on the government from the international community, however, no mention was made of the consequences of a proposed negotiation for a free trade deal with Mexico and the United States in

¹⁰⁴. David Beetham Bureaucracy (Minneapolis: University of Minnesota, 1987) p-72

¹⁰⁵. Toronto Star op. cit. June 25, 1992, p-A11

the winter of 1990-1991. Mexico's decision to give full patent protection for brand name multinational drug manufacturers, as a prelude to the beginning of free trade negotiations, forced the multinational pharmaceutical industry to openly renege on their promises under Bill C-22. The industry publicly declared that it "could unilaterally abandon the commitments it made to Canada in 1987 about increasing research and development spending here."¹⁰⁶ It also made it quite known that it was "in no way bound by previous commitments it had made in Canada."¹⁰⁷ The implication was that the industry must get the protection it wants. However, instead of reminding the multinational drug industry to keep its commitments under Bill C-22, the Minister of Industry, agreed with its position by declaring, "What was good in 1987 is no longer sufficient in 1992."¹⁰⁸

As a condition for beginning the North American Free Trade negotiations with Mexico and the U.S, the Mulroney government agreed to abandon its compulsory license provision for brand name drugs, while, at the same time, to support the multinational industry's efforts to include global intellectual property rights protection under GATT. According to the Toronto Star, the position of the government was that "even in the health care sector, the profit motive needs room to

¹⁰⁶. *ibid.*,

¹⁰⁷. *ibid.*,

¹⁰⁸. Toronto Star "Major side effect of Tory prescription is higher drug prices." December 1, 1992. p-A19

flourish."¹⁰⁹ and therefore, in keeping with their mandate, "to govern," any delay would jeopardize the proposed \$500 M in promised new investments by multinational drug firms "in moving toward international competitiveness which is crucial if we are going to achieve prosperity here in Canada."¹¹⁰ Bill C-91 was finally proclaimed into law on February 4th 1993. Ironically, the same day, the U.S Congress released a report calling for a reduction of monopoly patent protection for multinational drug companies in order to reduce prices.

The relevant parties who stand to be significantly affected by this legislation include; individual Canadians who need prescription medications, government and private insurance companies and government benefit programs which pay for the prescriptions medicines for senior citizens and welfare recipients, foreign owned multinationals represented by the PMAC and the locally owned generic manufacturers represented by the Canadian Drug Manufacturers Association.

The impact of Bill C-91 on the years of extended monopoly protection and its added costs to Canadian consumers can be seen in table 1. Its aggregate impact in constant and nominal dollars is outlined in table 2. (Both tables are taken from the Prime Institute study)

¹⁰⁹. *ibid.*,

¹¹⁰. *ibid.*,

Table 1. Impact of Bill C-91 on Years of Extended Market Exclusivity and Added Cost to Canadians

Generic Name	Brand Name	Manufacturer	Product Intro. Date	Years on Market to Dec-92	Generic Launch w/ C-22	Patent Expiry	Added Years of Monopoly	Added Cost 1993-2000 Nominal \$	Added Cost 1993-2000 93 Const. \$
enalapril	Vasotec	Merck (Frosst)	Aug-87	5.3	Aug-1994	Oct-2007	13.2	\$444,055	\$401,799
lovastatin	Mevacor	Merck (MSD)	Jul-88	4.4	Jul-1995	Feb-2001	5.6	\$200,973	\$181,799
omeprazole	Losec	Adria	Jun-89	3.5	Jun-1996	Dec-2008	12.5	\$149,340	\$133,924
simvastatin	Zocor	Merck (Frosst)	Aug-90	2.3	Aug-1997	Oct-2004	7.2	\$118,737	\$105,248
cisapride	Prepulsid	Janssen	Jan-90	2.9	Aug-1995	Mar-2002	6.6	\$101,155	\$91,267
lisinopril	Prinivil	Merck (Frosst)	Nov-90	2.1	Nov-1997	Oct-2007	9.9	\$97,614	\$86,525
lisinopril	Zestril	ICI	Nov-90	2.1	Nov-1997	Oct-2007	9.9	\$97,614	\$86,525
ciprofloxacin	Cipro	Miles	Jan-89	3.9	Jan-1996	Jul-2007	11.5	\$85,062	\$76,272
ondansetron	Zofran	Glaxo	May-91	1.6	May-1998	Mar-2008	9.8	\$83,292	\$73,183
ketorolac	Toradol	Syntex	Apr-91	1.7	Apr-1998	May-2001	3.1	\$69,180	\$60,850
cetirizine	Reactine	Pfizer	Jun-91	1.5	May-1998	Jan-2003	4.7	\$67,983	\$59,732
sumatriptan	Imitrex	Glaxo	Feb-92	0.8	Jan-1999	Aug-2005	6.6	\$56,766	\$49,442
pravastatin	Pravachol	Squibb	Oct-90	2.2	Oct-1997	Jul-2000	2.8	\$45,443	\$40,512
ceftriaxone	Rocephin	Roche	Jul-87	5.4	Jul-1994	Sep-2006	12.2	\$32,949	\$30,127
amlodipine besyl.	Norvasc	Pfizer	Jan-93	-0.1	Jul-1999	Jul-2010	11.0	\$30,532	\$26,593
iohexol	Omnipaque	Sanofi	Oct-85	7.2	Oct-1992	Oct-1999	7.0	\$25,622	\$23,973
alfentanil	Alfenta	Janssen			Feb-1995	Jul-1998	3.4	\$17,877	\$16,545
loratidine	Claritin	Schering	Jun-88	4.5	Jun-1995	Jan-2001	5.6	\$17,221	\$15,646
ketconazole	Nizoral	Janssen	Jan-85	7.9	Jan-1992	Nov-1996	4.8	\$16,032	\$15,381
ceftazidime	Fortaz	Glaxo	Sep-85	7.3	Sep-1992	Mar-2000	7.5	\$13,577	\$12,620
vercuronium	Norcuron	Organon	Jul-86	6.4	Jul-1993	Dec-1999	6.4	\$13,283	\$12,372
flunisolide	Rhinalar	Syntex	Feb-78	14.8	Feb-1993	Sep-2000	7.6	\$13,139	\$12,155
clarithromycin	Blaxin		Jul-92	0.4	May-1999	Aug-2004	5.3	\$13,785	\$12,029
sufentanil	Sufenta	Janssen	Jul-92	0.4	Oct-1992	Jun-1997	4.7	\$11,615	\$11,038
ticlopidine	Ticlid	Syntex	Sep-91	1.3	Sep-1998	Oct-2001	3.1	\$11,697	\$10,279
ofloxacin	Floxin	Ortho	Sep-91	1.3	Jun-1998	Jun-2001	3.0	\$11,467	\$10,138
cefuroxime	Ceftin	Glaxo	Aug-90	2.3	Dec-1997	Feb-2007	9.2	\$10,875	\$9,559
cefixime	Suprax	Lederle	Jan-90	2.9	Jan-1997	Apr-2005	8.3	\$9,614	\$8,529
betaxolol	Betoptic	Alcon	Jul-86	6.4	Jun-1993	Mar-1997	3.8	\$6,223	\$5,950
fluconazole	Diflucan	Pfizer	Sep-90	2.3	Sep-1997	Feb-2002	4.4	\$5,175	\$4,592
impinex-cilastatin	Primaxin	Merck (MSD)	Feb-92	0.8	Feb-1999	Nov-2001	2.8	\$4,983	\$4,341
flutamide	Euflex	Schering	Jan-85	7.9	Jan-1992	Jun-1994	2.4	\$4,320	\$4,287
idarubicin	Idamycin	Adria	May-91	1.6	Apr-1998	Nov-2008	10.6	\$3,981	\$3,499
mesna	Uromitexan	Bristol	Feb-89	3.8	Feb-1996	Feb-1999	3.0	\$3,114	\$2,839
enalapril/HCTZ	Vasoretic	Merck (Frosst)	Oct-90	2.2	Oct-1997	Oct-2007	10.0	\$1,985	\$1,760
nifedipine	Nimotop	Miles	Oct-89	3.2	Oct-1996	Dec-2007	11.2	\$1,371	\$1,230
fluoxetine	Prozac	Lilly	Jan-89	3.9	Jan-1996	Mar-1996	0.2	\$1,050	\$987
Total Added Cost (1993-2000)								\$1,898,700	\$1,703,547
Simple Average per Drug Entity				3.6			6.8	\$51,316	\$46,042
Wt. Average per Drug Entity (92% Sales)				4.1			8.0	\$151,609	\$136,768

Table 2. Cost Impact of Bill C-91 in Nominal and Constant Dollars

Year	<u>Cost of Bill C-91 in Nominal \$</u>				<u>Cost of Bill C-91 in 1993 Constant \$</u>			
	(New Drugs before 1993)		(New Drugs before & after 1993)		(New Drugs before 1993)		(New Drugs before & after 1993)	
	Annual \$	Cumulative \$	Annual \$	Cumulative \$	Annual \$	Cumulative \$	Annual \$	Cumulative \$
1993	\$6,523,000	\$6,523,000	\$6,523,000	\$6,523,000	\$6,523,000	\$6,523,000	\$6,523,000	\$6,523,000
1994	\$24,552,000	\$31,075,000	\$24,552,000	\$31,075,000	\$24,000,000	\$30,523,000	\$24,000,000	\$30,523,000
1995	\$61,524,000	\$92,599,000	\$61,524,000	\$92,599,000	\$58,962,000	\$89,485,000	\$58,962,000	\$89,485,000
1996	\$161,355,000	\$253,954,000	\$161,355,000	\$253,954,000	\$151,603,000	\$241,088,000	\$151,603,000	\$241,088,000
1997	\$253,644,000	\$507,598,000	\$253,644,000	\$507,598,000	\$233,640,000	\$474,728,000	\$233,640,000	\$474,728,000
1998	\$371,866,000	\$879,464,000	\$371,866,000	\$879,464,000	\$335,822,000	\$810,550,000	\$335,822,000	\$810,550,000
1999	\$477,655,000	\$1,357,119,000	\$477,655,000	\$1,357,119,000	\$422,900,000	\$1,233,450,000	\$422,900,000	\$1,233,450,000
2000	\$541,582,000	\$1,898,701,000	\$541,582,000	\$1,898,701,000	\$470,097,000	\$1,703,547,000	\$470,097,000	\$1,703,547,000
2001	\$474,145,000	\$2,372,846,000	\$561,950,000	\$2,460,651,000	\$403,492,000	\$2,107,039,000	\$478,213,000	\$2,181,760,000
2002	\$411,448,000	\$2,784,294,000	\$598,470,000	\$3,059,121,000	\$343,272,000	\$2,450,311,000	\$499,305,000	\$2,681,065,000
2003	\$360,562,000	\$3,144,856,000	\$630,983,000	\$3,690,104,000	\$294,919,000	\$2,745,230,000	\$516,108,000	\$3,197,173,000
2004	\$328,987,000	\$3,473,843,000	\$694,529,000	\$4,384,633,000	\$263,816,000	\$3,009,046,000	\$556,946,000	\$3,754,119,000
2005	\$263,124,000	\$3,736,967,000	\$674,255,000	\$5,058,888,000	\$206,863,000	\$3,215,909,000	\$530,086,000	\$4,284,205,000
2006	\$212,233,000	\$3,949,200,000	\$742,815,000	\$5,801,703,000	\$163,582,000	\$3,379,491,000	\$572,537,000	\$4,856,742,000
2007	\$175,570,000	\$4,124,770,000	\$687,648,000	\$6,489,351,000	\$132,670,000	\$3,512,161,000	\$519,623,000	\$5,376,365,000
2008	\$73,556,000	\$4,198,326,000	\$441,334,000	\$6,930,685,000	\$54,493,000	\$3,566,654,000	\$326,956,000	\$5,703,321,000
2009	\$30,814,000	\$4,229,140,000	\$1,109,293,000	\$8,039,978,000	\$22,380,000	\$3,589,034,000	\$805,690,000	\$6,509,011,000
2010	\$18,048,000	\$4,247,188,000	\$1,096,527,000	\$9,136,505,000	\$12,851,000	\$3,601,885,000	\$796,161,000	\$7,305,172,000
1993-2000		\$1,898,701,000		\$1,898,701,000		\$1,703,547,000		\$1,703,547,000
2001-2010		\$2,348,487,000		\$7,237,804,000		\$1,898,338,000		\$5,601,625,000
1993-2010		\$4,247,188,000		\$9,136,505,000		\$3,601,885,000		\$7,305,172,000

These estimates are provided by the renowned Prime Institute of the U.S.¹¹¹

According to it, in 1993 Canadians would pay at about \$6.5 M in extra costs. (Also it is important to look at the analysis of the New York Times and the estimates provided Frances Lankin, Ontario's Minister of Health on page 14.) However, the costs of Bill C-91 will grow over the next few years. By the year 2000, the added costs of Bill C-91 compared to the continuation of Bill C-22 will be \$470 M annually. The projected cumulative cost from 1993 to 2000 will be \$1.7 billion, and by the year 2010, it will increase to \$3.6 billion. According to a report, this added cost is without consideration for new compulsory license generic drugs that would begin in 2001 for patented products introduced to the Canadian market in 1993 and beyond. If one considers the effects of these new products in the first decade of the next century the "cumulative costs from absence of lower-cost C.L generics by the year 2010 would jump to \$7.3 billion."¹¹²

Bill C-91, according to the calculations of the Prime Institute, will "result in a three to one payback in eight years and a seven to one pay back (and up to a 15-to-one) over 18 years,"¹¹³ to brand name companies in return for \$500 M in promised investments in research and development. Canadians would be better off if the

¹¹¹. Stephen Schondelmeyer (Prime Institute.) The cost of Bill C-91. An Economic Impact Analysis of the Elimination of Compulsory Licensing of Pharmaceuticals in Canada. (Minneapolis: College of Pharmacy, University of Minnesota) January 21, 1993.

¹¹². *ibid.*, p-6

¹¹³. Prime Institute. *op.cit.* p-7

government had retained the previous provisions under Bill C-22 and subsidized the proposed \$500 M in research and development rather than extending the monopoly patent protection of brand name companies.

The consequences of the Conservative government policy took less than two months from the date of the passing of the drug patent legislation act into law to materialize. A report by the Patent Medicine Prices Review Board (PMPRB), based in an examination of 177 of the highest demanded drug products being sold, confirmed that 77 - or 43 percent of those products are sold at the highest or second highest prices compared to other nations of the world.¹¹⁴ Only Germany and the United States are reported to have an average higher price of brand name drugs.¹¹⁵ According to the Globe and Mail, during the heat of the debate on the merits of Bill C-91, prices of prescription drugs increased 2.6 percent for the first six months of 1992 compared to a rate of inflation of 1.5 percent.¹¹⁶

The effectiveness of the PMPRB can be seriously questioned, given the fact that it was supposedly given additional powers to police excessive price increases by the brand name drug industry. The present guidelines of the board restrict "introductory prices of new, breakthrough drugs to the international median price for

¹¹⁴. Toronto Star "Drug prices in Canada among top in world." April 1, 1993. p-A15

¹¹⁵. *ibid.*,

¹¹⁶. Globe and Mail "Study cites high cost of drugs in Canada." March 31, 1993. p-A1 and

the same drugs,"¹¹⁷ The board has indicated that it wants "to expand its mandate in order to hold the maximum introductory price of all new drugs to the international median."¹¹⁸ According to the Board's chairman, Harry Eastman, "I would make the observation that our prices are a good deal higher, and this question ought to be addressed by appropriately adjusting our guidelines."¹¹⁹ However, a spokesman for the PMAC has sharply rejected any proposed changes to the Board's guidelines by saying "We recognize there should be fair pricing policies, but we don't agree with this knee-jerk approach that what's good for Europe is good for Canada."¹²⁰ The PMAC in other words is saying that it doesn't matter if it is selling the same drugs cheaper in Europe than in Canada.

This "knee jerk" approach has so far cost the multinational industry over \$5 M in fines for exceeding price guidelines. Nonetheless, in response to the 'policing' by the Patent Medicine Review Board, some brand name companies have given up their patent protection on certain drugs rather than submitting themselves to the PMRB guidelines. This permits the companies involved to sell their drugs at whatever prices they desire since, under the new regulation of Bill C-91, it would

¹¹⁷. Globe and Mail op.cit. March 31, 1993. p-A2

¹¹⁸. ibid.,

¹¹⁹. ibid.,

¹²⁰. Toronto Star op.cit. April, 1993. p-A15

take generic companies at least five years to get federal safety approval.¹²¹

Conclusion.

The changes to Canada's intellectual property rights protection laws were linked to a number of factors; namely the increase in investments and profits by the multinational drug industry since the passing of the 1969 legislation, the advent of the Conservative government, free trade, NAFTA, and to some extent the role of Quebec. Nonetheless, it should be noted that although Quebec played quite a significant part in the changing of the 1969 legislation, it did not have much say in the decision-making process for Bill C-91. This position will be explained in the conclusion.

¹²¹. Toronto Star "Drug firms must pay up for overcharging." January 4, 1994. p-

Chapter 4

Internationalization of Intellectual Property Rights, the role of the U.S. and Canada.

General Introduction.

A general understanding of the role of the state in seeking extensive international intellectual property protection rights as a global policy instrument on behalf of multinational pharmaceutical companies is pivotal in understanding the power and influence of the industry and of state-business relations. Its impact on the policy process in Canada and in developing and less developed countries are more significant, especially since for the first time in history, nation states are obliged to obey intellectual property rights on a global scale without consideration of their level of economic and technological development and the social consequences. In liberal industrialized countries, the early phase of capitalism as a system was dominated by the efforts of individual capitalists who fought to expand their personal wealth by augmenting their share of the market. For Marx, the development of the market mechanism was fundamental for the coming into existence of the capitalist system. The market, he predicted, would be undermined by the growth of monopolies through the control of technology, resources and labour.

The world capitalist economy has gone through many important structural

changes over the past century; the greatest of which has been the impact of the contemporary scientific and technological revolution,¹ which has boosted the level of production and efficiency within the free market economy. As a consequence of the fierce competitive nature of the free market economy those multinational corporations who dominate and control the sciences, according to Mandel, becomes progressively "the prisoners of capital."² This tendency results in the preponderance of large monopolies to control the productive process, such as the pharmaceutical, auto, oil, electronic and computer industries.

Consequently, a contradiction between the motives and the growth of scientific development and the social needs of the population is quite evident. More especially, increasing social demand and need for adequate access to scientific innovation and research is prevented by the inherent inclination to hold the sciences captive of profit making enterprises. This accounts for the rise of pharmaceutical and other TNC's, which not only dominate the marketplace but also the state policy process in their best interests. Marx, in the Communist Manifesto, quite amply bemoaned the fact that capitalism which claims to defend private property of the means of production, in reality expropriates the private property of a large number

¹. Ernest Mandel Late Capitalism (London: Verso Publications, 1980.) p-249.

². *ibid.*, p-262

of people transforming it into a few monopolies.³

The speedy merging and concentration of many pharmaceutical industries, from hundreds three decades ago to just about twenty dominant corporations at present, is a good case in point. Capitalism was born out of free competition. Nevertheless, according to Ernest Mandel, "free competition produces concentration, and concentration produces the opposite of free competition, namely, monopoly."⁴ Through monopoly control, the market is mutually divided, production is then limited to maintain high prices and thus exercise influence on the policy process. Therefore, the rules of a free market economy are not and cannot be applied.

As Marx would argue, because of a persistent and developing crisis in capitalist relations of production largely due to the contradiction between capital and labour, we witness over the past years the advent of a number of recessions, stagflation, the debt crisis, fall in profits, international competition and chronic alienation of the work force. New and interesting phenomena have developed in the 1990's, that is, the advent of globalization and the introduction of the global recognition of Intellectual Property Rights as a major international public policy tool for multinational corporations. This can be described as an attempt to extend the

³. Karl Marx and Freidrich Engels The Communist Manifesto (London: Penguin Books, 1986) p-86

⁴. Mandel, op.cit. p-249

market mechanism to the control and privatization of ideas, knowledge, "from life forms to the application of mathematical equations,"⁵ to agricultural products, seeds and even medical procedures in the hands of a few dominant corporations. In other words, not only the means of material production but also the means of intellectual production are being converted into global private property. Therefore, economic exploitation is not only totalized, even worse it is globalized.

Of significant concern is the linking of intellectual property rights to the application of patents of altered animals, plants, genetic materials, and inventions. Through the usage of DNA technology, multinational corporations are about to use and manipulate life forms in the creation of industrial products for commercial profits.⁶ For example Dr. Freda Rajotte explains,

Toxic genes can be inserted into plants to make them distasteful to pests. Transpecies organism such as "geep" (a mixture of goat and sheep) can be produced. Animal characteristics can be inserted into plants.[For example, the phosphorescence from glow worm has been inserted into tobacco plants to make them glow in the dark.] Human genes can be inserted into sheep so that they produce pharmaceuticals in their milk.⁷

The tampering with human life form, the monopoly of knowledge, ideas etc., for the purpose of making profits raises serious questions as to what extent are

⁵. Maude Barlow and Bruce Campbell Take back the Nation (Toronto: Key Porter Books, 1993) p-105

⁶. Ecumenical Coalition for Economic Justice. Intellectual Property Rights in NAFTA (Toronto: Ecumenical Coalition for Economic Justice, 1993) p-23

⁷. Ecumenical Coalition for Economic Justice, op.cit. p-23

multinationals willing to go to control and manipulate the sciences for their own benefits. More significantly, there is a pronounced shift from an industrial based economy to an information-based one. As a result, capitalists are looking at new ways of accumulating capital by tapping into a new source of wealth by privatizing knowledge as intellectual private property. This potential of controlling a new "well" of wealth has encouraged multinational corporations to campaign for a new regime of global intellectual property rights. According to the U.S. International Trade Commission, multinational corporations will gain \$100 billion annually from greater intellectual property rights protection.⁸

Globalization and Intellectual Property Rights.

The concept "Intellectual Property Rights" became more prominent in the American policy agenda shortly after the collapse of the Eastern and Soviet "Socialist" States. For some, America had lost its 'imperial throne' as protector of 'free nations' and the task ahead for American policy makers was to concentrate on how to stem the falling tide of their economy. The post-world war economy of U.S depended mainly on 'handouts' and subsidies from the state to invest in the military industry. After the collapse of the so-called Socialist bloc, attention was focused on the competitiveness of American industries and ways to protect American property rights as a result of falling profits. Another factor that has played into the hands of

⁸. Canadian Centre for Policy Alternatives. The Tory Wreckord (Ottawa: CCPA, 1993) p-

policy makers is a consequence of new information technology of which the U.S. has been rated as the leading innovator; fears are expressed that open access to these innovations on the world market would undermine American economic dominance of the world economy.

Other analysts described the new surge in intellectual property right as a result of the globalization of the world's economy. They claim the increasing interdependence of nation-states demands greater control and leverage to protect intellectual rights if the international competitiveness of industries is to be preserved. The subjection of advanced capitalist states to this new rigid prescription of competitiveness is an attempt to establish a new regime of international capital accumulation for American multinational corporations. To understand the roots of this issue, an appreciation of the concept of globalization and how it can be used to help multinational corporations to intervene in the domestic economy of nation states is essential. John Shields and Stephen McBride define globalization as characterized by three features:

the first is the creation of larger markets-the nation-state can no longer satisfy the needs of multinational corporations, so big business is demanding larger trading areas; second, in this new environment capital has become increasingly mobile; and third, there has been greater global specialization of production.⁹

While David Held describes globalization as a new

⁹. John Shields and Stephen McBride Dismantling a Nation (Halifax: Fernwood Publishing, 1993)p-20

international order involving the emergence of a global economic system which stretches beyond the control of a single state (even of dominant states;) the expansion of networks of transnational linkages and communications over which particular states have little influence; the enormous growth of international organizations which can limit the scope for action of the most powerful states; the development of a global military order...which can reduce the range of policies available to government and their citizens.¹⁰

This new direction of political and economic policy means that dependent developed states like Canada and other developing and less-developing countries will have no alternative but to shed the remnants of their protectionist policies and experience the hard realities of capitalist market development. Failure to do so will cast them as outcasts of the new international economic order and thus run the risk of isolation and exposure to collective punishment from the 'international community'. A good example in point is CUSFTA and NAFTA.

The new global order requires the rapid transnationalization of nation-states and their political, social and economic institutions. This will manifest itself in a new approach to democracy, where dominant institutions and agencies of the international economic community under the influence of multinationals will be given priority over domestic institutions in the policy process in the interest of capital. An important adage to the concept of globalism is the internationalization of the role of the state particularly among developed nations. More especially, there is

¹⁰. David Held "Democracy: From City-States to a Cosmopolitan Order?", Political Studies, XL, Special Issue, 1992, p-32-4. cited in Leo Panitch in , Globalisation and the State. Socialist Register (London: Merlin Press,1994). p-62

an effort to reconstruct state-civil society relations to enhance the accumulation of capital on behalf of transnational corporations, to the detriment of the previous social and Keynesian welfarist role of the state. This process has not by any means bypassed the role of individual developed states, but rather it has witnessed the active participation of these states that includes the support of "highly politicized sets of capitalist classes hard at work,"¹¹ to promote these changes domestically.

The objective is to constitutionalize and guarantee the global and domestic rights of capital through international treaties, for example, intellectual property rights through GATT, NAFTA and FTA. Leo Panitch argues that globalization is a process that takes place under the aegis of states. According to him, the globalization of international states,

is encoded by them and in important respects even authored by them; and it involves a shift in power relations within states that often means the centralization and concentration of state powers as the necessary condition of and accompaniment of global market discipline.¹²

This is necessary to further the process of accumulation of capital and to enhance the economic rights of multinational corporations.

Before the 1980's, there were no international bodies or organizations with the full international abiding authority to implement, enforce or settle intellectual property disputes. It has been argued that traditionally, individual nations took the

¹¹. Panitch. op.cit. p-65

¹². Panitch. op.cit. p-64

responsibility under the guidance of the World Intellectual Property Organization (WIPO) in determining the appropriate level of intellectual protection depending on their social and economic needs. In cases of disputes, several international treaties, such as the Berne Convention for Protection of Literary and Artistic Works and the Paris Convention for Protection of Industrial Property, provide the basis of mediation. Therefore it was quite natural that the "international regime" for the protection of intellectual property rights would be criticised by a determined and aggressive U.S. administration dedicated to the strengthening of intellectual property rights.

At the beginning of the 1980's it was estimated that about fifty countries around the world did not recognize protection for patents.¹³ International agreements to protect intellectual property came under the jurisdiction of the World Intellectual Property Organization, the Berne Convention and the Paris Convention. The Reagan Administration, acting on behalf of the concerns of multinational drug corporations, expressed its abhorrence that "the system of intellectual property protection worldwide had grown seriously out of whack, and drastic action was required to restore it to an even keel,"¹⁴ and pledged to have greater worldwide

¹³ . United Nations, Transnational Corporations & Management Division. Intellectual Property Rights and Foreign Direct Investment. (New York: United Nations, Department of Economic and Social Development. 1993) p-12

¹⁴ . Ralph Oman Intellectual Property After the Uruguay Round. (New York: Journal Copyright Society of the U.S.A). Vol 42, No.1, Fall 1994. p-19

intellectual rights for its businesses.

World Intellectual Property Organization.

The World Intellectual Property Organization (WIPO) was established on July 14, 1967 and came into existence in 1970. In December 1974 it became a specialized agency of the United Nations. Membership is based on nation-states that are members of the Paris and Berne conventions or of the UN or any of its specialized agencies. The objectives of the WIPO are to promote protection of intellectual property rights through support of treaties and the modernization of local domestic laws. However, it has no legal bidding authority to impose IPR laws on any state. Membership of the WIPO includes over 101 states.

Berne Convention.

The Berne Convention is administered by the WIPO and is an international treaty established since 1886. It provides protection of literary and artistic works and is also considered the most important institution for international copyright protection. However it must be noted that there is no specific international law that renders worldwide copyright protection. Copyright protection is based on laws of individual states based on principles and rules established by the Berne Convention. The U.S. has persistently refused to join the Berne Convention and has consistently been accused by its European trading partners of violation of their copyright protection laws which cost their creators millions of dollars. Robert P. Benko explains that "the U.S. decision not to participate (in the Berne Convention) was

motivated by a wish to preserve certain formalities, including registration requirements, and to preserve such protectionist measures as the requirement of manufacture in the United States."¹⁵ The United States also refused to recognize the "moral rights" of authors that protect their works against editorial distortion. Since the inception of Berne in 1881, the U.S, "has been able to enjoy protection without offering reciprocal rights to members,"¹⁶ while American authors can obtain Berne rights protection by first publishing their work in a Berne member country. The United States' refusal to recognize the intellectual property rights of other countries became a major obstacle to its efforts to introduce new intellectual property rights laws within the WIPO and later GATT.

Paris Convention

The Paris Convention, established in 1883, is considered the oldest international treaty designed to protect intellectual property rights. The principal motive of this organization is to protect industrial property through patents, trademarks, service marks, trade names, industrial designs, utility models, indication of source and appellation of origin. The Convention since its establishment is based on the requirement that the same protection be given to nationals of member states as to one's own nationals and that foreigners be given equal access to the local

¹⁵ . Robert Benko Protecting Intellectual Property Rights. (Washington, D.C. American Enterprise Institute for Public Policy Research, 1991) p, 4-5.

¹⁶ . *ibid.*,

judicial system to pursue cases of violation of property protection rights.¹⁷ Again, as Robert Benko explains, the "United States does not belong to numerous industrial property agreements, generally for one of three reasons: the agreement violates U.S. Law; U.S. law is stronger; or the agreement is not in the interest of the United States."¹⁸

Historic International Evolution

In 1981, several amendments to the patents and trademark agreements governed under the WIPO were proposed by members of the group of 77, a trade body within the United Nations, with support from Canada, Turkey, Australia, New Zealand, Portugal and Spain. It was suggested that a study be undertaken on the merits of intellectual property rights. According to the Group of 77, the granting of trademark rights on pharmaceuticals would be a detriment to the international community since it creates a monopoly situation that causes prices and profits to rise. It therefore called for the elimination and prohibition of the use of trade marks for pharmaceuticals.

The group of 77 also proposed to amend patent agreements to allow the automatic granting of compulsory licences

¹⁷ . Ronald Berenbeim Safeguarding Intellectual Property. (Washington: The Conference Board, 1989) p-4

¹⁸ . Benko, op.cit. p-5

After thirty months of nonmanufacture or non production by the patent holder, to permit compulsory licences that give the licensee exclusive rights to use the patent in a country while the original patentee is denied use for up to two and one half years, and to provide for forfeiture of a patent after five years of not working in a country.¹⁹

Some developing countries also threatened to pass legislation if the above recommendations were not approved. In the meanwhile, alarm bells were already rung by multinational drug companies, who were concerned about any unilateral action taken by developing countries and especially with Canada's support that could threaten their monopoly position on the world market. Canada had already challenged multinational drug corporations by introducing compulsory licensing in 1969. The position of developing countries, and of Canada, was that the price to be paid for the transfer of technology from industrialized countries was prohibitively expensive because of intellectual property rights restrictions. These restrictions further the disparity between the developed and developing world and hinder the developing world's effort to modernize its economy.

The U.S. government, under pressure from pharmaceutical multinationals, countered the Group of 77 proposals by calling for greater protection of intellectual property rights. It initiated discussions within the WIPO in the early 1980's with this objective in mind but their efforts failed by the mid-80's. The Americans were

¹⁹. Benko, op.cit. p. 9-10

extremely dissatisfied with the "WIPO's egalitarian climate."²⁰ They complained that too much attention was paid to the interests of developing countries. Finally after failing to force its agenda on other nations, the United States concluded that "the World Intellectual Property Organization was institutionally unable to forge a new consensus."²¹ A U.S. Deputy representative of trade sums up the U.S. position on the WIPO by noting that

we have worked hard for more than (fifteen) years at the WIPO to develop new standards [of protection]. To date, these efforts have been frustrated. It would be ill-advised for us to continue relying on the WIPO to solve serious and pressing trade distortions.²²

Angered by the "egalitarian climate" within the WIPO, the U.S. government took unilateral action against states that violate its intellectual property rights and proposed to use GATT as the body to enforce and enhance additional protection rights. However some developing countries continued to insist that the best institution to deal with the problem of intellectual property rights was the WIPO and not GATT.

²⁰ .Oman. op.cit. p-20

²¹ .ibid., p-22

²² . Michael Smith "The Uruguay Round and the Intellectual Property Agenda", in Intellectual Property Rights and Capital Formation in the next Decade. (ed). Charls E. Walker and Mark Bloomfield. (Washington, D.C: Landam, University Press of America) p-174

U.S. Actions to protect Intellectual Property Rights.

In 1984 the U.S. government amended section 301 of the Trade Act of 1974 to give the president the authority to impose import restrictions against states that violate the provision of adequate and effective protection of intellectual property rights. The act also included an evaluation of to what extent intellectual property rights are protected in order to qualify countries to benefit from U.S. Generalized System of Preferences (GSP) which provides duty free concession to many nations. States such as Canada that are beneficiaries of the GSP will be obliged under the law to prove that they protect American intellectual property rights adequately before gaining duty-free privileges.

In January 1985, the Reagan Administration appointed John A. Young, President and chief executive officer of Hewlett-Packard, to head the President's commission on Industrial Competitiveness. Mr. Young described in a report the impact on U.S. competitiveness of inadequate intellectual property laws and noted that the "strengthening of intellectual property rights at home and abroad should be a priority item on the nation's policy agenda."²³ Another Reagan appointee, Ed Pratt, President of pharmaceutical giant Pfizer, was put in charge of the President's Advisory Committee for Trade Negotiations (ACTN). Pratt played a major role together with White House officials in preparing a proposed multilateral intellectual

²³ . President's Commission on Industrial Competitiveness. Global Competition, the New Reality (Washington, D.C: mimeo, 1985) p-52

property agreement to be considered at the GATT talks in Uruguay.²⁴

The President himself got into the act of lending support to big business. In his address on September 23, 1985 on a "Trade Policy Action Plan" he instructed "the U.S. Trade Representative to accelerate negotiations with any and all countries where the counterfeiting and piracy of U.S. goods had occurred and to bring these practises to a quick end."²⁵ The President pointed out that "when governments permit counterfeiting or copying of American products, it is stealing our future and it is no longer free trade."²⁶ On April 7, 1986 the U.S government introduced as a top trade policy priority the Administration's Statement on the Protection for U.S. Intellectual Property Rights Abroad.²⁷ It called for

stepped up bilateral discussions with major infringer countries, work to have intellectual property included in a new round of trade negotiations, and a legislative package to address inadequacies in U.S. laws, through the "Intellectual Property Rights Improvement Act of 1986,"²⁸

²⁴ . Jacques Gorlin "The Business Community and the Uruguay Round". Charls E. Walker and Mark Bloomfield, op.cit. p-172

²⁵ . U.S. Department of State. "The President's Trade Policy Action Plan." Current Policy No. 745, September 23, 1985.

²⁶ . ibid., p-2

²⁷ . United States Senate. Committee on Finance. Subcommittee on International Trade. Intellectual Property rights: Hearing before the Subcommittee on International Trade of the Committee on Finance." United States Senate, Ninety-ninth Congress, Second Session, on S.1860 and S.1869, May 14,1986. United States Congress. (Washington: U.S., G.P.O. 1986) p 5-6

²⁸ . ibid., p-4

which was scheduled to be submitted by May 5, 1986 to Congress. The Administration also announced that as a matter of priority the issue of intellectual property rights would be included in bilateral discussions with Canada, Japan, Brazil, India, Indonesia, Thailand, Malaysia and Mexico. Reagan was especially concerned about Canada and had already, in his meeting with Prime Minister Brian Mulroney in March 1985 in Quebec City, expressed his opinions on the protection of multinational pharmaceutical intellectual property rights. Mulroney reportedly promised to look into the issue.

Role of Multinational Drug Industry on Intellectual Property Rights.

The effort of multinational drug and other businesses to commend their policy agenda to the U.S. government was hardly a difficult task. The extraordinary political influence of businesses to persuade the American state to adopt policies to help their world-wide economic interests challenges the myth of too much government interference and regulation of business activity in U.S. Evidently the state acts as a loyal servant to the interests of capital in using its political, economic and military muscle to remove barriers and hindrances which other states and nations may pose to the expansion of its own capital; in this case, U.S capital.

The efforts of multinational corporations to influence the movement of capital and expansion of markets are quite evident in the following table taken from Ronald Berenbeim's Safeguarding Intellectual Property. As the survey reveals, nearly all the surveyed companies are working to increase or maintain intellectual property

protection while only six intend to reduce protection. Twenty-three companies would prefer to maintain current levels of protection under the Paris convention while thirty seek to raise the level. The companies that would prefer to maintain or reduce intellectual protection are those that are not dependent on intellectual protection for their survival.

Table 1: Profile of Companies Working to Influence Intellectual Property Safeguards.

		Company is working to:		
<i>Treaty, Law or Convention</i>	Number of Companies	Increase Protection Number	Maintain Protection Number	Decrease Protection Number
Gatt	59	49	8	2
Berne Convention	33	24	9	-
Paris Convention	53	30	23	-
WIPO	52	37	14	1
EC	46	35	11	-
Bilateral agreements	39	32	5	2
Home country laws	66	58	8	-
Foreign laws	48	44	3	1

According to a study conducted by the OECD the Economic Costs of patent infringement to the chemical and pharmaceutical industries were an estimated \$7 to \$8 billion annually, while economic losses to all OECD-based industries in 1992

accounted for an estimated \$70 billion or 3 percent of the value of world trade.²⁹ According to U.S. companies in 1986 they have lost about \$25 billion in sales to infringement of patents, copyrights and trademarks.³⁰ It has been suggested that these figures are calculated on the bases of what the chemical and pharmaceutical and other industries could have earned if there were stronger intellectual property protection laws. The alleged losses of the pharmaceutical industries are enormous, since it has consistently been rated as the most profitable industry in the U.S. While American companies complained of a substantial loss in 1986, yet according to the following table, the International Trade Commission in a study of 168 U.S. companies in 1986, they have lost just about \$100 million in fourteen countries that were reluctant to recognize or enforce intellectual property rights. Again to add up to the reported \$25 billion in losses would mean including every country in the globe which is very unlikely.

²⁹ .Organization for Economic Cooperation and Development. Globalization of Industrial activities: 4 Case studies: Auto Parts, Chemicals, Construction and Semi-conductor. (Paris: OECD, 1992) p-63

³⁰ .Timothy Richards "Intellectual Property Rights: Reconciling Divergent Views." in, Charles E. Walker and Mark A. Bloomfield, op.cit. p-98

Table 2. Fourteen Countries where 1986 Reported losses from Intellectual Property Protection Inadequacies Exceeded \$100 Million (168 U.S. Companies).

Country	Number of Firms Reporting Losses	Estimated Losses Reported
<i>(In thousands of U.S. dollars)</i>		
Taiwan	49	\$752,501
Mexico	41	533,435
Korea	53	496,090
Brazil	48	426,285
China	18	420,250
Canada	11	367,080
India	27	244,020
Japan	37	191,514
Nigeria	9	157,500
Hong Kong	13	153,725
Saudi Arabia	7	130,520
Indonesia	18	130,031
Italy	13	110,150
Spain	14	103,428

Source: International Trade Commission, taken from Ronald Berenbeim Safeguarding Intellectual Property op.cit. P-8

It is known that the U.S.-based Pharmaceutical Manufacturers Association had been trying ever since the 1969 Canadian Patent Act Amendment to get the Canadian government to rescind its compulsory licence provision. Compulsory licensing does not eliminate patent rights but it requires the multinational drug industry to compete by licensing local competitors in exchange for the payment of a royalty.

The pressure to deal once and for all with issues concerning intellectual property came from the U.S. private sector. In 1986, after tremendous lobbying by a powerful group of U.S. chemical and pharmaceutical industries, the computer, software, entertainment, electronic, and publishing industries, the U.S. government agreed to introduce intellectual property rights protection measures into the multilateral trade negotiations under the umbrella of the General Agreement on Tariffs and Trade.³¹ It was already recognized that efforts within the WIPO had been futile because of overwhelming opposition by developing countries to any changes in intellectual property rights protection. The driving force behind the private sector initiative came from the President of Pfizer, Edmund Pratt, who at the time of his appointment by President Reagan as head of the ACTN in 1981 initiated a proposal for a multilateral agreement under GATT.

According to Dr. Sylvia Ostry, the Advisory Committee for Trade

³¹. Ecumenical Coalition for Economic Justice, op.cit. p-9

Negotiations, later renamed the Advisory Committee for Trade Policy and Negotiations in 1988,

Is the top oversight committee and has played an active role in shaping the overall agenda of the Uruguay Round. This is especially clear in the case of some of the issues-services, trade-related intellectual property, and ...investment measures...[The] intellectual property issues...[are] probably the agenda item of highest priority to key sectors of the U.S. business community.³²

Linda McQuaig, author of The Quick and the Dead, notes that "Pratt used his entrée to the highest levels of power to get the issue of patent protection for brand name drugs -- under the guise of the protection of intellectual property -- onto the U.S. trade agenda."³³ According to Joe Calvin of the U.S. Council for International Business, Pratt was responsible for putting together a coalition of businesses with similar concerns on intellectual property rights representing the film, computer and pharmaceutical industries. They identified to U.S. policy makers a number of countries that were doing little or nothing to protect the rights of patented and copyrighted products.³⁴ They also showed how the U.S. was losing its "leading edge in some of the few areas where it still enjoyed supremacy in world markets."³⁵ Pratt and his coalition later enlisted the support and participation of prominent businesses

³² .ibid., p-10

³³ .Linda McQuaig The Quick and the Dead. (Toronto: Penguin Books, 1992) p, 154-156.

³⁴ .ibid., p-155

³⁵ .ibid.,

in Europe and Japan to form an alliance under the umbrella of the Union of Industrial and Employers' Confederation of Europe and (Keidanren) of Japan. Later he also helped to form the "Intellectual Property Committee," (IPC) a pressure group which would later play a major role in the negotiations of NAFTA. The vice president of Pfizer, C.L. Clemente, describes the role of the Intellectual Property Committee as

a group of major U.S. corporations seeking to mobilize support for improving the international protection of intellectual property. I think the overriding significance of that group is that it has been able to join together with our colleagues in electronics, in the traditional copyright fields, the chemical industry, and so on to present a united front on behalf of strong intellectual property protection. It is starting to pay dividends, both in the bilateral area and in the GATT. Certainly we intend to press harder on all fronts.³⁶

The IPC and UNICE wasted no time in laying out their position on what they wanted to achieve through international trade negotiations under GATT. For Pratt it was necessary to have "a code of minimum standards for copyrights, trademarks, patents and appellation of origin issues. And then, naturally an enforcement mechanism. And finally, dispute settlement."³⁷ Patrick Leahy, (a Democrat from Vermont) chairman of the Senate Judiciary subcommittee and member of the subcommittee on patents, copyrights and trademarks, conceded that protection of intellectual property rights has received increasing attention by Congress.

³⁶. C.L. Clemente "A Pharmaceutical Industry Perspective." op.cit. Charls E. Walker and Mark A. Bloomfield. p-134

³⁷. Ecumenical Coalition for Economic Justice. op.cit. p-10

According to him

American trade policy in the intellectual property sphere should turn on its head Theodore Roosevelt's advice to "to speak softly and carry a big stick. We should speak loudly about the importance of giving strong incentives to creators and inventors... in multilateral bodies such as the General Agreement on Tariffs and Trade."³⁸

With the formation of the IPC, the issue of putting intellectual property rights on the agenda of the Uruguay Round of GATT in Punta Del Este, Uruguay in 1986 got a further boost. Accompanying U.S. trade negotiators to the GATT talks was a delegation from Pfizer and other pharmaceutical and industrial lobbyists. According to the Ecumenical Coalition for Economic Justice, GATT serves as a "threat of cross retaliation," that is, withdrawal of market access for exports of goods from countries that do not enforce a standard of intellectual property rights sought by the IPC.³⁹ At the meeting, representatives from developing and less developed countries vehemently opposed any modification of international law to protect intellectual property rights under the umbrella of GATT and called for negotiations to take place at the appropriate body namely the WIPO. Despite their efforts, the issue of the competence of GATT to deal with intellectual property gradually won favour due to overtures and threats from the U.S.

At the commencement of the Uruguay talks, neither UNICE or Keidranren of Japan supported the American position on intellectual property in the GATT

³⁸ . Patrick Leahy "U.S. Congressional Approaches to Reconciling Intellectual Property Rights", op.cit.. Charls E. Walker and Mark A. Bloomfield. p- 78.

³⁹ . Ecumenical Coalition for Economic Justice. op.cit. p-10.

negotiations, because of American failure and intransigence in not supporting similar intellectual property protection rights for European and Japanese goods under the Berne Convention. It took almost two years for the American government, Pratt, and the IPC to convince the UNICE and Keidranren that in contrast to the WIPO the "enforcement mechanism and dispute settlement [of intellectual property rights] could be instituted through the GATT,"⁴⁰ since the WIPO "identifies with special interests of the very governments in the developing world who abet the theft of intellectual property."⁴¹ But this could not occur until the Americans promised to join the Berne convention and also amend their copyright laws and to respect European and Japanese intellectual rights under the Berne convention in exchange for their support at the multilateral talks of GATT.

As a consequence in June 1988, a joint statement by the IPC, UNICE and Keidanren (Japan) declared support for placing intellectual property rights in the current Uruguay Round negotiations of GATT. The statement called for

(1) effective, equitable and non-discriminatory enforcement of intellectual property rights; (2) dispute settlement procedures to insure that the domestic laws of GATT signatories include basic intellectual protection and enforcement procedures; and (3) preferential trade treatment for signatories to encourage adherence to GATT intellectual property protection standards.⁴²

Encouraged by the global unity among multinational corporations and states

⁴⁰ . *ibid.*, p-11

⁴¹ . *ibid.*,

⁴² . Berenbeim, *op.cit.* p-12

of the developed countries, the U.S. special representative to GATT, Congressman Sam Gibbons (Democrat, Florida) warned that now "if there is not a good response in the GATT talks, we will go ahead and unilaterally set up some pretty tough barriers and penalties for those who encroach upon the right."⁴³ The U.S. government, acting under pressure from pharmaceutical multinationals decided to heed Theodore Roosevelt's advice however not to "speak softly" but to wield the "big stick" before the conclusion of the GATT negotiations, by taking unilateral trade action under Section 301 of the U.S. Trade Act of 1984 (as amended in 1988), against governments that failed to implement stronger intellectual property protection rights for pharmaceutical manufacturers. A number of countries in Asia and Latin America, as well as Canada, were put on the "301 watch list." They were accused of retarding long term efforts of research and development and profits of multinational drug corporations.⁴⁴

To win concessions and support for their position on GATT talks, the Americans promised preferential access to their markets for countries that supported their initiatives through technical assistance, differential treatment and special transition rules. They also negotiated bilateral arrangements with over 30 countries for greater patent protection including Canada, South Korea, Taiwan, Singapore, Malaysia, Mexico, Colombia, Venezuela, Peru, Bolivia and Ecuador.

⁴³ . Sam Gibbons "U.S. Trade Legislation and Intellectual Property Rights". op.cit. Charls E. Walker and Mark A. Bloomfield. p-170

⁴⁴ . United Nations, Transnational Corporations, op.cit. p-12

Canada's Role under GATT.

The Canadian government did not, by any means, resist American threats to take retaliation under the "301 watch list"; rather it promised to institute greater intellectual property rights after the passing of Bill C-22. According to John Shields, co-author of Dismantling a Nation, in an interview with the author "part and parcel of the Conservative government policy was a commitment to the strengthening of continental ties through a deregulated market therefore, why should one be surprised?"⁴⁵ Nonetheless, the Americans were surprised how easily the Canadians gave in to their overtures. Canada's position on intellectual property rights, until the advent of the Conservatives to power in 1984, was traditionally supportive of developing countries as exemplified in its position in the Group of 77. Under the previous Liberal government, American and Canadian businesses encountered a protectionist administration under Pierre Trudeau. After the Conservatives took power in 1984 they found a more acquiescent trading partner. The Conservatives were also under pressure from business to initiate free trade talks with the U.S. The objective was to create better access for Canadian businesses to the U.S. markets while at the same time to strengthen and open the domestic market for more direct foreign investment.⁴⁶

⁴⁵ . John Shields Co-author of Dismantling a Nation. Interviewed by the Author. September, 1995.

⁴⁶ . Abraham Rotstein Intellectual Property and the Canada/U.S. Free Trade Agreement: The Case of Pharmaceutical. Intellectual Property Journal Vol. 8 No. 1. December 1993. p, 124-125.

The Canadian desire for free trade between Canada and the U.S. gave the Americans the opportunity to pursue the question of intellectual property rights with their Canadian counterparts. American displeasure over compulsory licences was raised by President Reagan to Prime Minister Brian Mulroney as a precondition to begin free trade talks already in 1985. In response the Mulroney government in 1986 introduced Bill C-22, which extended monopoly protection from 7 to 10 years. Nonetheless, the Mulroney government had some reservations about the public's perception of a possible link between free trade and changes to compulsory licensing for pharmaceuticals. The U.S. deputy chief free trade negotiator confirms this by noting that

Ottawa didn't want it (intellectual property) to be in the free trade negotiations. They didn't want to appear to be negotiating that way as part of the free trade agreement. Whatever changes they were going to make, they wanted it to be viewed as, quote, "in Canada's best interests",.... it was a high priority issue for us.⁴⁷

For the Americans it was very important to use Canada as a showcase to the rest of the world since a failure to obtain additional intellectual property rights protection from their closest and most important trading partner would be a blow to their international efforts against developing and less-developing countries. However, the level of protection provided by Bill C-22 was not sufficient for the Americans. According to a U.S., F.T.A. negotiator it would be "hard to use as a

⁴⁷. Quoted in Joel Lexchin *Pharmaceutical Patents and Politics: Canada and Bill C-22*. *International Journal of Health Services* Vol 23, Number 1. (Baywood Publishing Co, 1993) p-156

paragon to put over to the rest of the world."⁴⁸ James Baker, then Treasury Secretary of the Reagan Administration, saw the tale of events differently.

Canada will liberalize its rules on compulsory licensing of pharmaceutical. Canada will enact pending amendments contained in Bill C-22, and the Parliament will review within 10 years the further improvements for protection of pharmaceutical inventions... The disappointment of not getting a chapter [on intellectual property with F.T.A.] is off-set by the fact that the U.S. made no concessions in return for Canadian concessions.⁴⁹

Baker was obviously aware of the American position under GATT and NAFTA and knew that, sooner or later Canada and Mexico would be forced to make further changes to satisfy demands of pharmaceutical multinationals under the I.P.C. The American demands under F.T.A. can be described as moderate, taking into consideration the high level of political heat the issue has caused among Canadian politicians and interest groups. It has been argued that it would have been difficult for the U.S. to press for greater monopoly patent protection, since such a legislation would encounter difficulties by a Liberal controlled Senate. However, according to Abraham Rotstein, "On an International level the U.S. could not implement intellectual property rights, but within a regional bloc the U.S, as senior partner, had the opportunity to elicit superior gains, especially in the area of pharmaceuticals."⁵⁰ The opportunity to profit from greater intellectual property rights

⁴⁸ . Globe and Mail October 9, 1987. p-A2

⁴⁹ . "Confidential Appraisal of U.S/Canada Pact Weighs Benefits, Shortfalls". Inside U.S. Trade, Washington. Oct,9, 1987.

⁵⁰ . Rotstein, op.cit. p-125

within a regional bloc came with the beginning of NAFTA talks. Rotstein nonetheless was both right and wrong; the intention of the United States was to use its superior bargaining strength within NAFTA as a showcase to other nations within GATT of what it has achieved from Canada and Mexico. The Americans would therefore use their success within a regional trading bloc to exert more pressure on GATT to obtain greater internationally binding intellectual property agreement. American-based multinational corporations and the U.S government also had other reasons to push for greater intellectual property rights regionally since Mexico and Canada account for more than half of their total high-tech exports to the world.⁵¹

U.S exports in R&D intensive goods to Canada increased from \$6.6 billion in 1986 to about \$15.8 billion in 1990, while exports to Mexico increased from \$2.7 billion to \$5.3 billion in 1990. Copyright-Dependent exports from the U.S to Mexico and Canada totalled almost \$3 billion. This dramatic increase in U.S high-tech sales to Canada and Mexico encouraged the U.S government to campaign for greater protection of Intellectual Property Rights under NAFTA. Exports of R&D based products to both countries continue to increase at an alarming rate.⁵²

Given the information provided above, the Canadian position on intellectual property rights is still surprising especially since according to the International

⁵¹Office of the U.S. Trade Representative. Intellectual Property Rights-NAFTA (Washington ,D.C: August, 1992) p-1

⁵² .ibid., p-2

Trade Commission report {see table 2} in 1986 only eleven U.S. multinational firms reported losses of just \$367,080 in Canada due to inadequate intellectual property protection. Could the losses accrued to multinational corporations be so significant in the following years that they justified the Canadian government's decision to change its laws to appease U.S. interests at the expense of its domestic needs?

The TRIPS/GATT Agreement.

After nearly five years of negotiations, a draft agreement on Trade-Related Aspects of Intellectual Property Rights Agreements (TRIPS) also known as the Dunkel text was presented by the Director General of GATT, Art Dunkel, on December 20, 1991 as part of an agreement to be considered among members of the Uruguay Round. This agreement has been described as the toughest and most far-reaching of any existing treaties on the protection of intellectual rights. It would force most developing and less developed countries including Canada and some European countries to rewrite their laws. The TRIPS/GATT agreement covers all aspects of intellectual property rights and confirms universal minimum protection standards on corporate patents rights on drugs, seeds, forms of life, copyrights, trademarks, integrated circuits designs, industrial designs, trade secrets, appellations of origin and undisclosed information (know-how).

The draft treaty proposed that member states

1. grant patents to the inventor first filing an application (Article 9);
2. grant patent protection for products and processes in all fields of technology (Article 10);
3. provide a minimum patent term of 20 years from filing of the patent application (Article 22);
4. provide a grace period of one year for disclosures of inventors (Article 12);
5. accept patent applications satisfying certain minimum standards regarding content and format (Articles 3 and 4);
6. accept and give dates to applications in the English language (Article 8); accept and process related inventions in a single application (Article 5); require publication of applications a fixed time period after filing (Article 15); require courts to give a fair breadth of interpretation to patent claims (Article 21); and provide a reversal of the burden of proof for process patents (Article 24).⁵³

The proposed TRIPS agreement Article 30, also permits

limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interest of the patent owner taking into account the legitimate interests of third parties.

As well, governments under article 31(b) can "use the subject matter of a patent without authorization of the right holder" if such a use will be "to protect public health and nutrition and to promote public interest in sectors of vital importance to their socio-economic and technological development."⁵⁴ Finally less developed and some developing countries are given a transition period of about 10 years after the

⁵³ . Gorlin Jacques. "Update on International Negotiations on Intellectual Property Rights", in Wallerstein Mitchel, The Global Dimension of intellectual property rights in science and technology. (Washington: DC: National Academy Press, 1993) p-179.

⁵⁴ . data provided by the Hon. Lloyd Axworthy (Winnipeg, South Center) in, House of Commons Debates. p-14927. Dec 9, 1992.

agreement comes into effect to implement the laws. However, the U.S still reserves the right to take punitive action against any state within the so-called period of transition under Section 301 of the Trade Act. In conclusion, the TRIPS proposal prevents discrimination against a particular field of technology namely pharmaceuticals. It limits the use of compulsory licensing and establishes the minimum of 20 years patent protection.

The Canadian government did not make an alternative proposal to protect its domestic industries, rather it proposed to introduce the entire TRIPS text into NAFTA. Much to its surprise, however, the drug industry and the U.S. government objected. They were not pleased with the draft proposals since they did not meet all the demands of the Intellectual Property Committee. The Bush and Clinton Administrations both criticised the proposal and objected to the phasing in period of about ten years before the agreement takes effect. The multinational drug industry in a letter to Clara Hills, the U.S. trade negotiator, demanded that under any agreement of NAFTA, Canada must be forced to "dismantle its discriminatory compulsory (generic) licensing regime for pharmaceutical products and to suspend the granting of any compulsory (generic) licences from Dec. 20, 1991, and onward."⁵⁵ While the I.P.C. in a letter to Hills emphasised that the TRIPS text "should be considered as a floor -- not a ceiling -- for the level of protection that must be included in NAFTA'S

⁵⁵ . *ibid.*,

section on intellectual property."⁵⁶

According to Linda Diebel of the Toronto Star the NAFTA agreement satisfies the I.P.C demands as follows:

1. Big drug companies will be able to protect their "process" as well as their product, making it virtually impossible for generics to import in bulk and manufacture in Canada.
2. Patent holders will have to be found guilty of breaking competition law-a formidable task in Canada - before generic licenses will be granted.
3. Sweeping new criminal charges will be laid against patent breakers based on the revolutionary notion (for Canada) that they are guilty until proved innocent.
4. New rules on trade secrets will make it impossible for generics to duplicate a drug without duplicating all the clinical testing. That makes it tougher for generics in Canada than in the United States. The United States provides 20 years of patent protection, but it doesn't require generics to repeat the entire testing process for their products. They simply have to prove bio-equivalency.⁵⁷

As already mentioned, the GATT talks had not yet concluded and the TRIPS agreement (Dunkel text) was only submitted for consideration among members of GATT. Nevertheless, the decision by Canada and Mexico to join NAFTA certainly put pressure on a number of developing and less developed countries to accept the TRIPS agreement, in addition to the harassment and threats from the U.S government. Finally, with a few minor changes, however not to the total satisfaction of the drug industry but to satisfaction of U.S demands, the TRIPS text was signed by some of the major developed countries by January 1, 1995. However some

⁵⁶ . Toronto Star "How U.S. drug lobby put new patent law atop Canada's Agenda." December 6, 1992.p-A7

⁵⁷ . *ibid.*,

developing and less developed countries are yet to sign the agreement.

The NAFTA agreement on intellectual property rights supersedes the TRIPS proposals, as Linda Diebel had already noted, to the satisfaction of the multinational drug industry as some of the following examples demonstrate.

NAFTA Article 1709:7 and TRIPS Article 27.1 confirm the minimum patent protection of 20 years from the date of filing. But, Article 1702 of NAFTA, unlike the TRIPS text, permits governments to extend monopoly patent protection for more than 20 years on condition according to Article 1709:12 if there is a need "to compensate for delays caused by regulatory approval processes."⁵⁸ The multinational drug lobby chairperson, Judy Erola, wasted no time in hinting a few days after the passing of Bill C-91 that the multinational drug industry could not guarantee its promised investments. It can be recalled that the alleged reason for promoting changes to Canada's intellectual property rights laws was the need to encourage greater foreign investments by the multinational drug industry. Erola claimed that other countries in Europe and the U.S, are increasing monopoly patent protection to compensate for delays in the regulatory process and unfortunately Canada would still be at a disadvantage. Dr. Joel Lexchin, one of Canada's best known critics of the drug industry and author of The Real Pushers, told the author⁵⁹

⁵⁸ . Ecumenical Coalition for Justice Report, op.cit. p-18. Also see, Roy Davidson "Intellectual Property", in Duncan Cameron and Mel Watkins.Ed. Canada under Free Trade. (Toronto: J.Lorimer, 1993) p-21

⁵⁹ . Joel Lexchin author of The Real Pushers and Pharmaceuticals, Patents and Politics. Interviewed by the Author. June 5, 1995.

that before the scheduled parliamentary review of the drug industry takes place in 1996, he expects the multinational industry to begin its campaign to have an increase in monopoly patent protection to 25 years. According to him "they will get it,"⁶⁰ alluding to the power and influence of the industry.

Another significant achievement for the multinational drug industry over the TRIPS text as noted by Ecumenical Coalition for Economic Justice is the provision of "pipeline protection" for pharmaceutical and agricultural chemicals as of July 1, 1991 and January 1, 1992, respectively. This means that under Article 1709:4, if a patent for a drug is acquired by a pharmaceutical company in the U.S after July 1, 1991 but has not yet been marketed in Canada or Mexico, it automatically receives patent protection for the duration of the life of the patent. Therefore, pharmaceutical companies are no longer required to apply for patent protection in each country. The senior vice-president of the U.S. Pharmaceutical Manufacturers Association noted the inclusion of the NAFTA clause of pipeline protection as a "a key element important for all adequate patent laws [and] a major advance over the ... TRIPs text."⁶¹ Finally the Office of the U.S Trade Representative in Washington in its report on Intellectual Property Rights- NAFTA confirmed that "NAFTA provides a higher standard of protection for patents, copyrights, trademarks, and trade secrets than has

⁶⁰ . *ibid.*,

⁶¹ . Ecumenical Coalition for Economic Justice, *op.cit.* p-18

been established in any other bilateral or international agreement."⁶²

Foreign Investment in R & D and Transfer of Technology in Canada.

As already noted in Chapter 3, the basis of promoting greater intellectual property rights in Canada by the multinational drug industry was a promise to invest \$400 million over five years in building a biomedical research industry, which accordingly will permit Canada to compete with other countries. Yet after having attained 20 years of monopoly protection, the pharmaceutical industry publicly announced that it is still not satisfied. According to Judy Erola "Canada is [still] the odd man out."⁶³

The relationship between foreign investment and protection of intellectual property rights is widely contested. According to Michael Wilson, former Minister of Industry, Science and Technology and International Trade "Canada's international competitiveness in attracting new investments to the pharmaceutical industry will be enhanced by strengthening patent protection for the multinational pharmaceutical industry,"⁶⁴ this translates to greater intellectual property rights. The validity of this argument is challenged by many. According to some, the protection of intellectual property rights is an essential component in the decision making process within the

⁶² . Office of the U.S Trade Representative. op.cit. p-1

⁶³ . Ottawa Citizen "Drug makers won't guarantee research funds: New bill not good enough, official says", January 20, 1993, p-A3

⁶⁴ . Government of Canada. News Release, GATT Intellectual Property Measures Endorsed. (Ottawa: Consumer and Corporate Affairs Canada, 1992)

board rooms of transnational corporations on whether to invest. Some have argued that the transfer of technology and investment in R & D will not be forthcoming if there wasn't adequate protection. According to the Pharmaceutical Manufacturers Association of Canada (PMAC), "The most critical factor in ... investment decisions is a country's framework for the protection of intellectual property."⁶⁵ Past history of Canadian monopoly patent protection laws has already indicated a moderate increase in investments by pharmaceutical multinationals despite the introduction of compulsory licensing. Others have also argued that greater intellectual property rights regulations would not necessarily increase foreign investments.

A number of research and development based transnational corporations regard the protection of intellectual property rights as only one of the factors that is taken into consideration in influencing foreign investments. Factors such as the structure of supply and demand, size of the market, price level of products, economic growth, stability, low costs of skilled labour and technological capacity are important determinants in any decision to invest. According to the vice president of an important medical products firm,

⁶⁵ .Pharmaceutical Manufacturers Association of Canada. Towards Canadian Pharmaceutical Patent Law Reform. (Ottawa: PMAC, 1993) p-2.

Intellectual property rights protection in a particular country is important to (us) and is a consideration in deciding whether to invest or transfer technology to a joint venture or subsidiary. But it is only one factor and each case must be evaluated on its own merits. Other important factors to (us) are (A) size of the market for our key products; (B) desire of the local customers to have products made locally versus imported; (C) health care reimbursement policies of the country in question; and (D) the need for a technical presence in the country to support the sales effort and educated key opinion leaders/customers in the use of our products.⁶⁶

The Vice President of a major pharmaceutical firm confirms the above statement by saying that:

It has always been difficult to ascertain precise measurements on the relation between intellectual property and investments, and it would certainly be disingenuous to suggest that pharmaceutical patents by themselves will determine our investment in a country. Pricing levels for pharmaceutical, the ability to register products with the local health authorities, and assessment of growth opportunities in a country related to demographic factors, serve along with pharmaceutical patents as chief determinants in our decision-making process.⁶⁷

The above statements by executives of the pharmaceutical and medical industries confirm the reasons why Canada has historically been a relatively unattractive location for foreign investments in pharmaceutical research regardless of the introduction of compulsory licences in 1969. As already indicated, the Canadian domestic market for multinational drug companies is only 2 percent of the world market. Subsidiaries of multinational drug companies in Canada are branch plants and therefore are not in a position to make decisions on the allocations for research and development. These decisions are made at company headquarters.

⁶⁶ . data cited from interviews conducted by Edwin Mansfield in, Intellectual Property Protection , Foreign Direct Investment and Technology Transfer. (The World Bank, Washington; DC: 1994) p-25

⁶⁷ . *ibid.*,

According to Gail Vilensky, a special assistant to President George Bush, Canada because of its close proximity to the United States "doesn't have to worry about having a biomedical research industry - they can make use of ours."⁶⁸ For her, Canada gets "something of a free ride. That's what it means to be a small country next to a large country."⁶⁹ However, despite the Canadian support for new intellectual property rights protection laws, some drug companies would not by any means transfer their technology. According to the Vice President of a leading multinational drug firm, his company

does not transfer leading-edge technology in its usual course of business. When such transactions have occurred, intellectual property laws have not been a critical factor in deciding whether we will transfer leading-edge technology to a foreign country.⁷⁰

This statement negates the Conservative government's dream of attracting new investment in a high-technology industry.

Studies on Brazil, Italy, and Turkey have proven that greater intellectual property protection is not a factor that translates into larger foreign investments. In 1949 Brazil abolished product pharmaceutical patents and twenty years later process pharmaceutical patents. Despite protests and condemnation from pharmaceutical multinationals, foreign pharmaceutical investments continue to grow

⁶⁸ . Toronto Star op. cit. December 6, 1992.p-A7

⁶⁹ . ibid.,

⁷⁰ . Mansfield. op.cit.p-28

at the highest rate of all Brazilian industry. Foreign investment increased six times between 1971 and 1979. In 1980 the share of total sales of foreign firms averaged 29 percent in the pharmaceutical industry next only to tobacco which ranked at 73 percent. Again this information belies the argument that lack of intellectual property protection provided the bases of huge losses to the industry. Now with extended protection for monopoly patent rights for twenty years the pharmaceutical industry would rank at the highest category in terms of sales.

In 1939 patent protection was abolished in Italy and reintroduced in 1978. Between this period the national Italian pharmaceutical industry grew rapidly and became an important source of exports and imports of drugs. However, as a result of the introduction of patents in 1978 the national pharmaceutical industry control of the market decreased from 48 percent in 1979 to 41 percent in 1988. In contrast foreign companies increased their market share by 200 percent in seven years. However the most significant change that took place affected the Italian trade balance in medicines and pharmaceutical form a surplus of \$40.6 million in 1978 into a deficit of \$826.8 million in 1989.

Turkey abolished both process and product patents in 1961. However, the absence of patent protection did not in any way impede the development of the pharmaceutical sector. Foreign Direct Investments in the pharmaceutical sector rose to the largest percentage in any sector of manufacturing. According to Arman Kirim, "In 1979 around 23 percent of the total foreign capital stock was accounted for by

the pharmaceutical industry alone... It is clear from the data that... in these industries the presence of patents does not affect the increase in FDI."⁷¹

Conclusion.

One can conclude from some of the evidence raised above that multinational drug corporations under the TRIPs and NAFTA agreement would increase their monopoly power and ability to exhort higher profits from their technology, free from state intervention and at the same time able to operate however they choose in any given territory. The irony is that the protection of intellectual property rights smacks of protectionism rather than true competitiveness among industries under the banner of freer trade under NAFTA and GATT. The ultimate beneficiaries are U.S multinationals who through their branch plant operations already charge high fees for sharing their technology at the expense of consumers in Mexico and Canada. These companies also earn more through the repatriation of profits and the higher transfer prices which subsidiaries pay when they buy from the parent companies.

Finally, the industry was so pleased with the level of protection from competition under NAFTA that in a letter to Clara Hills, the U.S trade negotiator, they publicly praised her. According to the letter,

⁷¹ . Transnational Corporation & Management Division, Department of Economic and Social Development. Intellectual Property rights and Foreign Direct Investment (New York: United Nations, 1993) p.27-28

The provisions of the intellectual property chapter of the NAFTA agreement represent a significant advance in the standards of protection and enforcement of intellectual property rights that have been negotiated by the United States to date." "You ...can be justifiably proud of your achievement."⁷²

⁷². Toronto Star December 6, 1992. op.cit. p-A7

Chapter 5

State, Public Policy and Bill C-91

Mulroney and Bill C-91

The advent of the Mulroney Conservatives into power in 1984 signalled a shift in Canada's public policy away from the pro-nationalist domestic policies of the previous Liberal government. Moreover, Mulroney's macroeconomic policy was driven by the party's ideological distaste for state intervention and Trudeau's centralist approach. Mulroney's reign in power was guided by the effort to remove all impediments that stifle the competitive nature of businesses. In a major policy announcement in New York weeks after winning the election, Mulroney in an address to the Economic Club, an exclusive grouping of over seven hundred top business representatives of the U.S., proclaimed his government's new economic policy. The dominant motto was Canada is "open for business. " Mulroney announced the demise of the National Energy Program and the renaming of the Foreign Investment Review Agency as Investment Canada with new goals to encourage foreign investment. He also praised the U.S. under the leadership of Ronald Reagan as a model for Canada and promised to tear down all barriers of trade between Canada and the U.S.¹ At the "Shamrock " summit, months later, with Ronald Reagan he promised to initiate free trade talks with the U.S. and meanwhile to revise Canada's Drug Patent Laws.

¹. Maude Barlow Parcel of Rogues (Toronto: Key Porter Books, 1990) p-vi-vii

Mulroney's assumption of political power was especially significant to Quebec and big business. In the 1984 elections his Conservatives took fifty-eight out of seventy-five seats in Quebec, compared to a single seat in 1980. Their share of popular votes increased from 12.6 percent in 1980 to 50.3 percent in 1984, while the Liberals dropped from 68.2 percent in 1980 to 33.4 percent in 1984.² One of the main reasons for Mulroney's triumph was a shift in financial support from big businesses to the Conservative party. The 1988 election was yet another victory for the Mulroney Conservatives. Again the province of Quebec played a significant role even though the Conservatives received fewer votes from Quebec compared to the 1984 election.

Mulroney's penchant for supporting big business and especially foreign investment above the interests of the local domestic sector was quite evident by the end of his term in office. According to Investment Canada, statistics illustrate that of \$122.5 billion of foreign direct investment between 1985 to 1992, an appalling 92% was spent to take over Canadian businesses and only 8% was used to create new business.³

Already before assuming political power Mulroney had signalled his support for greater intellectual property protection for multinationals and particularly for more investments in Quebec. During the infamous debates on Bill C-22, Mulroney

² , Roger Gibbins Conflict and Unity, An Introduction to Canadian Political Life. (Toronto: Methuen, 1986) p-269

³ . National Party of Canada. How to solve Canada's Economic mess? Mimeo. 1992

skilfully played the "Quebec Card" to shut up opponents of the multinational drug industry by arguing that the opposition Liberals were against foreign investments in Quebec. His outbursts managed to silence many Liberal MP's and Senators, to pass Bill C-22 and to prepare the terrain for future debates on further extension of intellectual property rights in favour of multinational drug companies. It was Mulroney, as leader of the Conservative Party, who was responsible for playing up the "regional issue" against other provinces for partisan political purposes much to the delight of Quebec nationalists and the multinational drug industry which was the original architect of the policy.

When changes to Bill C-22 were announced in January 1992, Mulroney and drug company lobbyists already knew that the passage of Bill C-91 was inevitable, since the Conservatives held the majority in both the House of Commons and in the Senate. Mulroney's "Quebec Card" played on behalf of the multinational drug industry, came in handily during debates on Bill C-91 once again. This time it was the press, with the help of prominent Quebec politicians, which used the Quebec issue to create further divisions among provinces and the federal government, by highlighting the fact that Quebec was the odd man out in support of the industry against other provinces who were lamenting having to pay higher drug bills and were not getting any new investments in return.

The press failed to deal with the real ramifications of Bill C-91 and the consequences of Canada's international actions within GATT and NAFTA and the

impact on the local generic industry and the health care system. The media, instead choose to "regionalize the issue," in a sensational manner. The press, like politicians and members of the drug industry, brought the "us and them" attitude into the furore of the debate. The multinational drug industry was portrayed as the victim who only wanted to help Canada by investing "in our development," while the regional opposition and social activists across Canada were seen as opposing a boost for Canada's scientific and technological development.

Liberal Party and the Government on Bill C-91

The attitude of the Liberal party seemed from the very beginning to be a half-hearted response to Bill C-91, which was a tacit acceptance of the preference for more branch plant investments at the expense of the development of the local industry and concern for the social and economic consequences. During the debates on Bill C-91 in the House of Commons, the position of the party was defined by Ron MacDonald (Dartmouth), Lloyd Axworthy (Winnipeg South Center) and Marlene Catterall (Ottawa West) and other members who vehemently opposed the bill. Other key members of the party for example Jean Chretien, (Shawingan) John Manley, (Etobicoke North) Andre Ouellet (Papineau Saint-Michel) and Paul Martin (La Salle-Emard) kept a low profile on the issue. It can be argued that the Liberals in an election year did not want to threaten business financial support for their party and its Quebec constituents. For example, Jean Chretien did not at any time during the Bill C-91 debates offer any substantial comment on the issue. Possibly he was

mindful of the "centralist" role he had previously played in the patriation dispute.

Others point to a division among the ranks of the party on the issue.

In response to a question posed by the Vancouver Sun to all the contesting political parties on whether they would repeal Bill C-91 if they won the 1993 elections, the Liberal party position was as follows:

The Liberal Party opposed the elimination of compulsory licensing because of the detrimental effects it is anticipated to have on drug prices in Canada and the competitiveness of the drug manufacturing industry. While recognizing the contribution of multinational, brand-name pharmaceutical manufacturers in the fields of research and development the Liberal party supports the review of the Patent Act in order to deal more satisfactorily with their retroactivity provisions of the legislation, and the powers of the Patented Medicine Review Board.⁴

The review of the Patent Act as promised by the Liberals, according to many top sources of the party whom I have spoken to, was called off until after the Quebec referendum. Deryck Lee, MP for Rouge River, Scarborough confirms this to the author. According to him, "Quebec is a major factor of consideration,"⁵ and he is confident that after the referendum the issue will be reopened for discussions in the House of Commons. Brenda Drinkwalter of the Canadian Drug Manufacturers Association supports this view and feels that the main stumbling block to a resolution of the problems arising out of Bill C-91 is the attitude of the government

⁴. Vancouver Sun "Party prescriptions for bill C-91; favouring drug companies at the expense of the ill". September 27, 1993. p-A5

⁵. Deryck Lee, (Scarborough, Rouge River) Member of Parliament, Interview by author. Scarborough, May, 1995.

of Quebec which "is proving to be a very difficult challenge."⁶ However, not all members of the party readily agree with this explanation. Dennis Mills, (Etobicoke North) Parliamentary Secretary to the Minister of Industry told the author that "it is absolutely not true,"⁷ rather the reason for the government's delay in reviewing the bill is that "it is simply not possible for governments to tear up international agreements overnight," and "they need time to assess the effectiveness of the bill."⁸

However, talks about having a review on Bill C-91 brought a swift response from multinational drug investors who have again threatened to withdraw all investments in Canada if the law is amended. Bloc Quebecois member Michel Gauthier (Roberval) supported the multinational drug industry by noting that any change in the law would "strike a lethal blow to the Quebec pharmaceutical industry."⁹ The Industry Minister responded by saying that "this government is not going to be blackmailed by threats."¹⁰ Nevertheless, any hope of a change in policy regarding Bill C-91 was laid to rest by the Industry Minister who told parliament that "we've signed on GATT and we've proclaimed NAFTA. That should be

⁶. Brenda Drinkwalter., Director, Canadian Drug Manufacturers Association, Interview by Author. Downsview, Toronto, May, 1995.

⁷. Dennis Mills, (Broadview-Greenwood) Member of Parliament and Permanent Secretary to the Minister of Industry. Interview by Author. Toronto, September 1995.

⁸. *ibid.*,

⁹. The Montreal Gazette. "Ottawa won't throw out drug bill, minister says." April 29, 1994. p-B2.

¹⁰. *ibid.*, p-B2

adequate to allay concerns that international investors have."¹¹ Manley's interpretation of the reasons for the review is to examine the impact on prices and how much the brand-name industry has kept up to its promise to invest more in research and development. It is the hope of many generic firms that some aspects of the law that are not covered by international trade agreements, for example the retroactive provision of Bill C-91, which dates from December 1991 could be changed. This could be a reasonable expectation by generic manufacturers. Nonetheless any hope of having a major change in policy would be wishful thinking since the political and international economic conditions are not appropriate.

Multinational drug companies, as already described in Chapter 3, skilfully used the Quebec issue to win a tacit silence on Bill C-91. The response from provincial leaders outside Quebec was relatively quiet. It seems that they accepted the federal and multinational explanation of the need for more intellectual protection for foreign investments in spite of their loud denunciations of having to pay higher health care bills. They also seemed not to want to create regional tensions in the wake of the Meech Lake negotiations.

¹¹. *ibid.*,

Role of the Multinational Industry in the policy process.

The basic tenet of liberal democracies rests on the notion that the individual is the most important consideration, above the interests and needs of society, and societal interests should not impinge on those of the individuals. In today's society the preference of individualism is more evident in the allocation of political power since those with a majority of capital investments are able to control and direct state power and economic policies to their own benefit. The public policy process is therefore held captive to the interests of capital. Another factor or component of economic power of businesses in Canada can be explained from the effects of the National Policy. For many years, Canada had been dependent on foreign multinational corporations for its economic development in the scientific and technological field. The resultant effect on Canada's public policy is the predictable interference of the U.S. government in the decision making process in Canada to favour their investors and their interests internationally. This inherent dependency inevitably has from time to time conflicted with the nation's social policy with regards to pharmaceutical policy.

The production of pharmaceuticals is decided by the owners of the means of production. Its operation in Canada functions within a branch plant dependent economy. Therefore its ownership direction, investment policy, level of research and development, prices, costs and distribution are determined at the corporation's headquarters. The economic and political power of the industry is dependent on its

ability to control, maintain and create the market through extended intellectual protection from competition and to resist government's regulatory intervention by using its financial and international influence on the state. The industry achieves its aims through threats and warnings of layoffs, withdrawal of technology, reduction of investments in R & D and interference of the U.S. government which is not unique to Canada.¹² It also uses its financial muscle to win public support through advertising and influence over the media.

While the market system is an important component to its existence, monopoly control strengthens its dominance on public policy because of its command of resources, technology, capital and the consumer market which it translates to maximum profits. Therefore, it is not surprising that the industry is ranked as the most profitable in the world. The excessive profits of the industry emphasizes a contradiction which Marx identified as a motive to increase power and influence through mergers and takeovers as a tool of further dominance for more profits which puts it against the social interests of society. Therefore, it creates a contradiction of poverty in the midst of wealth.¹³

Despite the introduction of compulsory licenses in 1969 the growth and expansion of the industry was not affected. Rather, it had to carefully plan its

¹². Gary Gerreffi The Pharmaceutical Industry and Dependency in the Third World. (Princeton: Princeton University Press, 1980)

¹³. Patricia Marchak Ideological Perspectives on Canada. (Toronto: McGraw-Hill Ryerson Limited, 1975) p-61

strategy on a long term basis. By investing more during the period of 1969 to 1987 it created an inevitable dependence and as a result, it strengthened its bargaining power within the policy process both national and internationally, since Canada provided a bad example for the industry's long term goal of greater intellectual protection worldwide. The industry is also careful in its selection of investments in regions and in its dealing with the state. Its objective is first of all to weaken state authority by using divide and rule tactics pitting regions against regions as in the case of Quebec and other provinces (see chapter 3). Initially it carefully builds an investment base in Quebec and silently as it withdraws or transfer some of its investment for example to Ontario it alerts the Quebec government to do more to guarantee its future in the region. This provokes a policy crisis with regards to the industry within the Liberal and Conservative parties. This attention- seeking plot successfully introduces the Quebec element in the policy process with a 'deja vu' of Quebec nationalism and reinforces Quebec's distaste of the control by the Federal government and other provinces of its industrial drug policy.

The power and authority of the state were greater during the 1960's because the industry did not yet establish a base in Canada as well as for other reasons which will be discussed in the conclusion. Therefore, the state was successful at setting rules, guidelines and regulations to confront the industry. However, as the branch plant industry becomes more integrated in the local economy it develops greater links with local elites and other forces to gain support to fend off control of

the state in the presumed best interest of the nation as was explained in Bill C-91.

The determination of public policy under Bill C-91 failed to adhere to the pluralist vision of the state as a neutral arbitrator. It also challenges the myth that power is equally distributed and divided among interest groups and that the electorate is adequately represented in the decision-making process. The existence of interest groups says little about their power and influence. The government's majority-backed parliamentary committee set up to investigate the consequences of the legislation failed to listen to well over 50 organizations opposed to the bill and used time limits to restrict the participation of the few that managed to present their cases against the bill which lasted for only three days.¹⁴ To prevent debate on the Bill in parliament the government used closure to silence its opponents.

Despite a plethora of protests, the state still defended its position by stressing only the economic benefits which it perceives Canada will gain against the social concerns raised by a number of groups. The government's position in preference for the interests of big business mirrored the role of the bureaucracy on the issue. This we will discuss in our conclusion. Finally in conclusion, the Marxian and elitist analyses both confirm that state power is held by a small group in order to exclude the majority from the decision making process. The above verifies as a Canadian paradigm the influence of multinational corporations on the nature of the formulation of state policies. In the general conclusion, this will be specified more precisely.

¹⁴. Toronto Star November 27, 1992

Conclusion

Considering the objectives formulated in the introduction of this thesis, we have now to review their analytic merits and scientific veracity. In Chapter One, we have described and analyzed some of the important aspects of the multinational drug industry and its social and political impact on human health and the state. There is no doubt that a number of factors, mentioned in this chapter, were not known to the public, and were not explained in detail by various government officials, politicians, and by the official mass media, especially by those who affirm the status quo. Specifically in the context of the industry's history, its structure, its role in research and development, safety, promotion, its marketing techniques, profits, power and influence; most of these were not publicized in an honest scientific manner.

As we demonstrated, the industry's history is characterized by many cases of blatant deceit and insatiable hunger for profits through vague promises, deliberate falsification of data and disrespect for human life, health and safety. It has always been careful to avoid any criticism. On the contrary, it defended its track record on the basis that its existence, and thus the health of millions, would be threatened if the state sought to regulate its operations. From a financial point of view, there is no evidence that the industry's existence has ever been uncertain, or that in any way it has been affected negatively by the expanding globalization of the world market.

The multinational drug giant is one of the few industries that consistently succeeds in making some of the highest profits in the world. At the same time,

there is no evidence whatsoever that shows that the costs of its research and development impede its financial success. Yet, it has claimed exactly the opposite, that it is permanently threatened, and therefore urgently needs state intervention in pushing for extended intellectual monopoly property protection rights. However, the credibility of the industry still lingers on a pedestal, since it has yet to prove to the public that its 'costly' R & D program is effectively utilized to produce new drug therapies or inventions, and not the "me too drugs," which it chooses to incorporate as part and parcel of its R & D program. Therefore, why should Canadians subsidize the research and development program of multinational corporations by paying higher prices for drugs, most which do not possess extra therapeutic value?

Apart from this, as already explained by the Marxian Theory, one of the major functions of the state in public policy is to guarantee economic stability, and to secure an environment suitable for investments. Hence, as is already evident, the multinational drug industry has no problems to convince the respective state authorities; neither to lobby for political support from the state, nor fear that the necessary legislation for intellectual property rights cannot be passed. It has to rather worry only about its public image.

For these reasons, the industry has been able to use its huge profits to finance an expensive promotional, advertising and marketing campaign once again, as we have seen chapter 1, to deceive consumers about the effectiveness and safety of its drugs and, at same time, to build an omnipotent image of its benevolence and what it is doing without alleged self-interest for the health of

humankind.

In Chapter two, we have analyzed various theories of the state and have taken into account various elements in our research work. We also explained the historical role of the Canadian state and public policy, which have consistently, since the National Policy, supported the interests of the accumulation of foreign and local capital. The latter can at best be illustrated by both the Marxian theory and to a lesser extent the elite theory of the state. In particular, the Marxian theory explains the essential role of the state and public policy in a capitalist society which is the promotion and protection of the rights of private property. As a result, the policy process through the state political and administrative systems becomes the focus of conflicts and debates between the property and non-property owning classes. Given our theoretical and public policy analysis of the Canadian state, its present and past actions in the decision-making process show that its primary function has been to guarantee the economic stability and environment suitability for foreign and local investments.

However, at issue in the Marxian analysis are the contending interpretations regarding the autonomy of the state in public policy from the interest of big business. Again, we would examine the differences of opinion to ascertain its impact on Canadian public policy. Ralph Miliband alleges that the ruling class in civil society and those who hold positions in state institutions give mutual consent and approval to each other in the decision-making process. Therefore, the instrumental needs of capital are met through the institutions of the state. Nicos Poulantzas does not support Miliband's thesis of a congruence

between the ruling classes of civil society and state institutions but rather sees the state as autonomous in its decision-making. However, different are the analyses of the two authors, the fact is they do not deviate from the basic Marxian principle that the main economic function of the state is to fulfil the needs of private property. What is at issue is how the Canadian state goes about fulfilling those needs.

Evidently the fragmentary nature of power and influence of capital varies according to the social, political and economic conditions of the moment and which political party is in power. This can be demonstrated through various actions and policies of the state for example from the introduction of the National Policy to the development of a Welfare State after 1945 to its present dismantlement. Nevertheless, the question of the autonomy of the Canadian state in public policy is debatable, more especially if we cannot answer the question of "autonomy from whom?" Can the state be autonomous from the influences of the dominant or ruling classes, special interest groups or the international economic and political system in the policy process? Again, this would depend on the social, political and economic conditions of the moment that determines which fraction of capital has the power and influence with the government in power. Our review of Canadian public policy has illustrated a general preference for the interests of the economic elites of both the U.S. and Canada compared to other interests whenever the state has to act on social policies and programs.

Proponents of the elitist analysis have also demonstrated that there is a

general ideological, social integration and shared economic congruence among decision-makers of the political and state systems which support the economic interests of a small group of people. The elitist theory is valuable to our analysis because it challenges the myths of equal opportunity and the state's neutrality in the policy process among all interest groups, it also questions the autonomy of the state from capital. Our analysis has revealed the weakness of the pluralist theory which tends to be rather simplistic and to emphasize only the process of decision-making but not the consequences and results of those decisions. It failed to consider that inequality in wealth translates to uneven political power and influence that favour the rich more than the poor. The Conservative government's decision to introduce greater intellectual property rights protection for foreign multinational drug corporations pierces the myth that the electorate is adequately represented by the government in power by virtue of its election which gives it a mandate to undertake whatever policy it wishes.

Concerning our analysis of Dependency Theory, the following should be noted. From the inception, Canada as a developed industrial nation was made economically dependent on the growth of multinational corporations for its economic development, in the scientific and technological fields. As a result, the Canadian policy process became a pawn of the U.S. government and of multinational interference and influence. Because of the global nature of modern day capitalism, it should be noted that the world market has a unifying and consolidating feature which agglomerates all developed industrial capitalist states, as metropolitan countries and which directly negates, as a result of the

international division of labour, all developing countries, and which affirms the already existing position of the developed nations. Therefore, to talk about 'independence' in policy-making of individual developed states for example Canada is something completely absurd. The state has no alternative but to develop as metropolitan countries to ever higher forms of accumulation of capital and technical know-how, which implies permanent monopolization, concentration, globalization and international protection of intellectual property rights. For these reasons, at present we experience the consolidation of developed capitalist states into the European Union and likewise Canada, Mexico and the U.S., under NAFTA. The main objective of this is the facilitating of the interests of capital globally to do whatever it wanted however it chooses to do without being impeded by local laws.

Concerning Chapter Three, treating the historical development of intellectual monopoly pharmaceutical patent rights and the role of multinational drug companies and state policy in Canada, it has to be noted that the industry has demonstrated similar disregard for consumers, and has consistently used threats and coercion to get what it wants. Since the state's 1969 policy to amend the monopoly Patent Act to permit generic competition, the industry has always held Canada as a renegade nation and a bad example to other nations because of its compulsory license provision. But, despite the introduction of compulsory licenses, the profit levels and expansion of the industry were not affected. Yet, as stated before, it held Canadians ransom, by linking the possibility of more investments to the granting of more protection. It also succeeded in using divide

and rule tactics, by exploiting historic ethnic French/English tensions, as a successful ploy to push its agenda. At the same time, it skilfully used the political process to its own advantage.

In the 1960's, the multinational drug industry in Canada was still relatively in its infancy. Although it did fight against the 1969 legislation, it was not successful. Apart from this, in the 1960's, the Canadian state faced almost a mini-rebellion from many groups and organizations representing the interests of different segments of the population on issues of better wages, recognition of trade unions, to too much American interference in the economy. Of importance was the growth of a new working class consciousness spurred by the actions of students, the women's movements, trade unions, intellectuals and the 'quiet revolution' in Quebec. Thanks to the Vietnam war, a tidal wave of anti-Americanism developed which gave birth to protests of too much foreign control of the Canadian economy, its institutions and cultural life. Also of major relevance during this period was the influence of popular culture on workers and youths and the anti-establishment feeling it created through protests that reigned against the status-quo. As a result, a number of legal and illegal 'wildcat' strikes, rallies, protests and violence dominated the mid-60's. The Canadian state, cognizant of the problems, was forced to be more active and interventionists in its attempt to resolve some of the problems it faced. As a result, 'another phase' of the welfare state was introduced through the recognition of collective bargaining for federal workers, and reform of Medicare and pension systems. Behind this background, the first amendment of the Patent Act was also introduced not only in response to

high prices charged to Canadian consumers but also as an attempt to demonstrate that the state could act 'independently' and decisively in the interests of the people.

Nevertheless, this does not mean that the state did not support other industrial projects at all. It simply meant that, because of the relative "youth" of the drug industry in Canada, it could not win sufficient support from the local political forces at that time. As well, the American government was too heavily occupied with internal problems arising out of the Vietnam war. Therefore, the government had an opportunity to demonstrate a nationalistic agenda which continued until the advent of the Mulroney government in 1984.

Despite the fact that Canadians managed to develop a home grown generic industry which saved them 30% to 40% in the price of drugs, legislation was passed once again to give exclusive monopoly intellectual protection rights for twenty years, almost twenty years later. Here again, one can notice the same inter-related and cooperative link between state, industry and profit-making as already mentioned.

Finally, another factor of consideration among many Canadian policy analysts is the part played by the bureaucracy in the decision-making process on intellectual property rights. Firstly, since bureaucrats are employed by the state, their obligation is to swear loyalty to it and to affirm its policies regardless of their consequences. Secondly, they perform their duties as state or civil servants, and not as independent masters. For this reason, their role can only be secondary and accessory to state demands. Any advice given to the state can only be in a

positive or negative way; in the latter case, this would signify a loss of their power. Thirdly, another aspect of their role, in the last decades, has been the historic tendency to expand itself, at the same time consuming a large portion of the state's budget. Also, because of its heterogenous character, it proved neither to be proficient, nor to be efficient. But, in recent times, as a result of the introduction of the new information highway, the bureaucracy is heading towards its own destruction, due to the globalization of the world economy. Finally, in this process of the concentration of capital, the huge army of bureaucrats itself is also being concentrated into a small highly specialized group of elitist state technocrats, who presently and in future, will really play the central role in decision-making and formulation of state policy in an overall globalized environment of the next century.

In Chapter four, we critically analyzed the historical process of the advent of intellectual property rights in the 1990's on a global scale. We also demonstrated the role of the multinational drug industry and in particular the role of the U.S. government, and Canada's active participation to institutionalize greater intellectual rights globally under GATT. But, despite this success, the industry was not satisfied and sought greater iron-clad protection under NAFTA which it used as a showcase to the rest of the world to silence its critics within GATT. The Conservative party had always given its full support to the multinational drug industries and therefore, on the assumption of political power, it did not hesitate to give exclusive monopoly intellectual patent protection rights. This is an excellent example to demonstrate the contradictory nature of the state,

depending on which political party serves whose political economic interests. In any case, this does not contradict the economic function of the state which guarantees maximum profits.

We have also shown the essence of globalized multinational co-operation; and within this framework we have demonstrated the political- economic alliance between industry and state. On the one hand, this encouraged the growth of economic power of multinationals; while, on the other, the political price which the state had to pay, was its own "withering away," although not in the sense predicted by Marx and Engels. In other words, its political power is progressively diminishing at the expense of the globalization of multinational corporations. The national state is not only losing its economic power to multinational corporations, but also its economic material base, previously guaranteed by nationalized industry and other state properties and services, which are now privatized and handed over to the same multinationals, leaving the state to survive on the crumbs of the taxpayers alone, mainly on the workers. Finally, in chapter five we have analyzed the role of the state, public policy and multinational corporations in Bill C-91.

With the above, we have summarized our objectives and have outlined the empirical theoretical verification of our main hypothesis. It remains to comment on certain related issues that result from this historical and critical analysis.

Given the background of our analysis it would be interesting to examine the validity of arguments made by many sources concerning the "Quebec factor" in the decision making process of the state. It has been demonstrated that Quebec

based politicians from both the Liberal and Conservative parties played a role in influencing changes in support of the multinational drug industry. It is not clear if they understood the social consequences of their actions or were just blinded by sheer nationalistic reasons.

But was the Quebec factor such an important issue in the decision-making process of the state as it is claimed to be? Step by step, in a chronological sense, evidence has already demonstrated the role played by the multinational drug industry in tandem with the United States government in order to pursue globally greater intellectual property protection rights. Arguably, Canada played a key role on the international scale by announcing its acceptance of the TRIPS Text (Dunkel Draft) on intellectual property rights immediately after it was announced. Thereafter, Canadians were informed by their government that Canada was obliged by the international community and not due to pressure from Quebec or for example, "the U.S." to increase intellectual patent monopoly rights for multinational drug companies. To help the government's credibility locally, the industry responded by showing support and rewarded Canada with a promise to increase investments in research and development to the tune of \$400 million over a period of five years, if the legislation would be passed. After much criticism from local sectors of the economy, the Quebec government came to the aid of the industry and the Federal government by declaring its support. Therefore, the 'Quebec factor' did not play a central role in the government's decision-making process, but was ideologically used by the industry and the state to play a "scapegoating" function to deviate attention from the real political and economic

issue at stake.

Statistical evidence has also revealed that the multinational drug industry is of no great strategic industrial importance to the Quebec region in terms of the number of manufacturing jobs that it creates. In 1985 it accounted for 1.2% of jobs in Quebec and forecasts by some analysts revealed that it would not reach 2 % by the end of the century. In addition, as a result of a number of mergers by the industry, it will be forced to close some of its operations in Canada and particularly in Quebec as is evident in the most recent merger between Glaxo and Wellcome Inc.(Glaxo Wellcome Inc.) The new company is already planning to sell its Montreal plant and transfer its manufacturing operations to Mississauga, Ontario. The future of the industry in Canada on the whole is in question because of the globalizing effects of the world economy, which includes continuing mergers and concentration of its research activities at head offices of multinationals which means loss of jobs in Canada.

Let us return to the political-economic game played by the state and industry, at the advent of the twenty-first century, with reference to the Canadian state and its drug industry. The Canadian economy is not suited for large scale investments in R & D because its market comprises only 2% of world-wide consumption. Also the industry already has worldwide international intellectual protection, so what guarantee do Canadians have that the multinationals will continue to invest in their economy, especially since they have already put up another condition for more protection, if Canada wants more investments in research and development? This blackmail is nothing new to Canadians, but will

the state assist the industry in its efforts once again? It is possible that it will, considering that the present Liberal government has so far failed to keep its promise to review the legislation.

Finally, concerning the future of the generic industry in Canada, we could make the following projections. Given the present weakness of the state, the long term survival and existence of the generic industry could be severely threatened in its very core, as a result of the new global control of technology within the world market. The massive economic and political power of the multinational drug industry, due to concentration and monopolization, certainly can easily destroy the generic industry through the gravitational force of its massive capital and highly developed technology, hence wiping out any form of weaker industrial competition, through absorption, suffocation, or simply, through takeovers. Therefore, it would not be surprising in a few years time to witness the gradual reduction and take over of generic competition by multinationals themselves.

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